The Development and Evaluation of the UCL-Diabetes Self-Management Programme (UCL-DSMP)

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ABSTRACT

This thesis describes the development and evaluation of two self-management interventions for patients with type 2 diabetes. The first (the UCL-DSMP) was a theoretically based group intervention, targeting the behavioural and psychosocial demands of diabetes. The second, which was not formally evaluated due to poor uptake, additionally included social support skills training and required attendance with a partner. Development included a systematic review of previous interventions including analysis of component efficacy, focus groups with health care professionals and patients, and piloting of the interventions. For each intervention a manual specifying content and facilitation techniques was produced.

The UCL-DSMP was compared to standard treatment in individuals with type 2 diabetes and microalbuminuria or proteinuria. Participants (n=124) completed assessments pre-intervention, immediately post-intervention (IPI) and at 3 and 9 month follow-ups. The UCL-DSMP significantly improved diet ($p<0.001$), exercise ($p<0.001$), and blood glucose monitoring ($p<0.001$) at IPI relative to controls. Results were retained for exercise and blood glucose monitoring at both 3 and 9 months follow-up ($p<0.05$). Diabetes specific quality of life was better in the intervention group relative to controls at all follow-ups ($p<0.05$). There were no differences on generic quality of life or psychological well-being.

Knowledge was improved by the intervention ($p<0.001$) as was behaviour specific self-efficacy ($p<0.05$), which was identified as a significant mediator of change in exercise ($p<0.05$) and blood glucose monitoring ($p<0.05$) at 3 and 9 months respectively. Illness beliefs, specifically belief in treatment effectiveness ($p<0.01$) and control ($p<0.05$)

improved following the intervention at IPI, however results were not retained in the longer term and beliefs were not significant mediators of behaviour change. No clear or consistent predictors of efficacy were identified.

These findings suggest the UCL-DSMP may be a useful intervention for patients with type 2 diabetes. Areas for further development and recommendations for clinical practice are discussed.

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ADDQoL	Audit of Diabetes Dependent Quality of Life
ANCOVA	Analysis of Co-Variance
ANOVA	Analysis of Variance
DFBC-II	Diabetes Family Behavior Checklist-II
HAD Sc ale	Hospital Anxiety and Depression Scale
HBGM	Home Blood Glucose Monitoring
IPI	Immediate Post Intervention
MDRTC	Michigan Diabetes Research & Training Centre
MSPSS	Multidimensional Scale of Perceived Social Support
OE	Outcome Expectancies
PANAS	Positive and Negative Affect Scale
QoL	Quality of Life
RTC	Readiness to Change
SCT	Social Cognitive Theory
SDSCA	Summary of Diabetes Self-Care Activities
SF-36	Short Form-36
SMBG	Self-Monitoring of Blood Glucose
SMI	Self-Management Intervention
SRM	Self-Regulation Model
TTM	Transtheoretical Model
UCL-DSMP	University College London – Diabetes Self-Management Programme

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CHAPTER ONE: MANAGEMENT OF TYPE 2 DIABETES

1.1 Structure of the Chapter

This chapter provides an overview of the challenge that diabetes presents to both the individual and the health care system, and examines the traditional management techniques that have been advocated for control of type 2 diabetes. The chapter begins by setting out the burden of diabetes in terms of prevalence and financial costs. A description of the different types of diabetes is then provided and a rationale given for why the current thesis will focus only on type 2 diabetes. Risk factors associated with the development of type 2 diabetes are discussed, as are the most common clinical and psychosocial impacts of the condition such as long-term complications and impact on quality of life and psychological well-being. The chapter then moves on to describing the traditional management of type 2 diabetes including both lifestyle recommendations such as diet and exercise behaviour and pharmacological management such as use of oral hypoglycaemics or insulin. The limitation of traditional approaches and in particular the problem of non-adherence to the diabetes regimen are discussed before a more recent approach, where emphasis is on self-management, is presented.

1.2 The Burden of Diabetes

Diabetes has been described as 'a rising epidemic' (Amos, McCarty & Zimmet, 1997). It has been estimated that between the years 2000 and 2030 the number of individuals with diabetes will rise from 171 million to 366 million worldwide (Wild, Roglic, Green, Sicree & King, 2004). Although the most marked increase will be in developing countries it is estimated that an increase will also occur within developed countries, with the most significant increase amongst individuals in the >65 yrs group. The UK is no exception and estimates of even a conservative 10% increase in prevalence of diabetes

in England and Wales by 2023 means that the 1.15 million individuals diagnosed with diabetes in 1998 in England and Wales will have risen to 1.66 million by 2023 (Newnham, Ryan, Khunti & Majeed, 2002). Such increases are due to a range of factors however the aging of the population and increases in obesity are particularly key.

The precise prevalence of diabetes in the UK is unclear but has been estimated to be between 1.6% and 3.7% of the population in a range of studies (Williams & Wild, 2003). These studies however rely on self-reported data, which may underestimate the prevalence of diabetes given the large numbers of individuals thought to be undiagnosed in the UK (Diabetes UK, 2000). It has been estimated that the number of people with undiagnosed diabetes may be equal to the number diagnosed in European populations (DECODE Study Group, 1998). There is therefore a need for more comprehensive data on prevalence of diabetes within the UK to provide a more accurate picture from which to determine the increase in prevalence and scale of the problem. This is also important given the association of diabetes with i) mortality, ii) morbidity and iii) increased health care costs.

It is well established that diabetes is associated with decreased life expectancy (Raleigh, Kiri & Balarajan, 1996). Estimates of the impact of diabetes on mortality rates however, have frequently been complicated by the under-reporting of diabetes as a cause of death on death certificates (Matthews & Pramming, 2003). A study by Manuel & Schultz, (2004) addressed this issue by using both a population health survey and linked diabetes registry. In this sample life expectancy for men and women with diabetes was 64.7 and 70.7 years for men and women respectively, reflecting 12.8 and 12.2 years lower life expectancy than for men and women without diabetes. The study also reported that health adjusted life expectancy (HALE) was 58.3 and 62.7 for men and

women with diabetes a reduction of 11.9 and 10.7 years compared to men and women without diabetes. This data is taken to reflect the significant impact of morbidity in diabetes, which occurs primarily from long-term microvascluar and macrovascular complications (see section 1.5 below).

Financial costs associated with diabetes in the UK are also high. In 1992 it was estimated that diabetes accounted for approximately 4-5% of total health care expenditure in the UK (Leese, 1992). By 1997 however this was recognised as a likely underestimate and readjusted to 8.7% with estimates that by 2011 total in-patient expenditure for diabetes would be 9.2% of total in-patient costs to the NHS, presuming no significant change in management or incidence (Currie, Kraus, Morgan, Gill, Stott *et al.,* 1997). Much of the costs of diabetes are associated with the long-term complications of diabetes. Recent publication of data from the United Kingdom Prospective Diabetes Study (UKPDS) has reported costs of several of the major complications of diabetes within the UK (Clarke, Gray, Legood, Briggs & Holman, 2004). It is estimated that for an individual with diabetes and a macro-vascular complication costs of non-hospital care would be double that of someone without the complication.

Given the current and increasing burden of diabetes, prevention and improved management of this condition is essential. For this to be possible an understanding of what diabetes is, risk factors for its development, and the impact of the condition is important. These topics are addressed briefly below (for more detailed discussion see Harris, Cowie, Stern, Boyko, Reiber *et al.,* 1995; Pickup & Williams, 1997).

1.3 Types of Diabetes and Classification

The characteristics that underlie all forms of diabetes are high levels of blood glucose (hyperglycaemia) and defects in insulin action. These are the result either of inadequate insulin secretion, insufficient insulin uptake or both. The two most common forms of diabetes are type 1 and type 2 diabetes, although there are a number of other rarer forms of diabetes such as gestational diabetes, which occurs during pregnancy, and other specific forms of diabetes which result from genetic defects in either β cell function or insulin action, or from diseases of the pancreas e.g. pancreatitis (The Expert Committee on the Diagnosis & Classification of Diabetes Mellitus, 1998).

1.3.1 Type 1 Diabetes

Type 1 diabetes is an autoimmune disease that results in destruction of the β cells in the pancreas. As a result individuals develop an absolute insulin deficiency and are consequently dependent on exogenous insulin. A further characteristic of this form of diabetes is the risk for ketoacidosis. This is a condition that can develop if blood glucose becomes uncontrollably high and can result in coma and death if not responded to. Sometimes ketoacidosis will be the trigger for diagnosis, alternatively type 1 diabetes may be diagnosed by symptoms of increased thirst, urination etc. Typically onset of type 1 diabetes is during childhood or adolescence and hence has sometimes been referred to as juvenile diabetes. In addition it has been referred to as insulin dependent diabetes due to the compulsory need for insulin. Both terms however have now been replaced with the term type 1 diabetes in a move to avoid confusion with individuals who have type 2 diabetes but take insulin or who have later onset type 1 diabetes.

1.3.2 Type 2 Diabetes

Type 2 diabetes is the most common of all forms of diabetes and affects approximately 85% of individuals with diabetes. It is characterised by a relative insulin deficiency, which is commonly the result of both insulin resistance and inadequate secretion of insulin from the β cells in the pancreas. Insulin resistance reflects the inability of insulin to exert its normal biological effects, which include promoting the uptake of glucose from the blood stream into peripheral cells, and suppressing the production of glucose from the liver. In individuals without diabetes an increase in blood glucose would trigger additional secretion of insulin from the β cells in the pancreas. In type 2 diabetes however dysfunction in the β cells means that not enough insulin to overcome the insulin resistance is secreted, and hence there is a shortfall in insulin levels with resulting hyperglycaemia. As insulin deficiency is not absolute in individuals with type 2 diabetes, exogenous insulin is not essential to survival, however increasingly individuals are being prescribed insulin to improve management of their condition.

Diagnosis of type 2 diabetes like type 1 diabetes may be by symptoms such as increased thirst and urination, headaches, sweating etc. However, not all individuals will experience such symptoms hence some cases are likely to be diagnosed incidentally, for example as the result of investigation for an infection, or when symptoms associated with one of the complications of diabetes presents. Hyperglycaemia may therefore go undetected for a sustained period, which has implications for the outcomes of diabetes including greater risk for developing both the microvascular and macrovascular complications associated with diabetes. It has been estimated that 30% of individuals with type 2 diabetes will already show some signs of early complications when they are diagnosed (Rajala, Laakso, Qiao & Keinanen-Kiukaanniemi, 1998).

Type 2 diabetes typically occurs in older individuals, usually over the age of 40 years, however recently there have been reports that type 2 diabetes is affecting increasingly younger individuals, including diagnosis in some children (Alberti, Zimmet, Shaw, Bloomgarden, Kaufman *et al.,* 2004). The increasing incidence of type 2 diabetes in young people is likely to be associated with an increase in obesity in the general population, which is a key risk factor for the development of type 2 diabetes. As with type 1 diabetes, type 2 diabetes has previously been known by different names and in particular non-insulin dependent diabetes, however this is no longer recommended given the increasing number of individuals with type 2 diabetes that use insulin for managing their condition.

Type 1 and type 2 diabetes are similar to the extent that management targets control of blood glucose levels, and both are associated with risk of micro and macro-vascular complications. A number of important differences between these forms of diabetes however mean the experience to the individual is likely to be different. The age of onset is a clear difference, individuals with type 1 diabetes have to cope with their illness throughout their life, and if diagnosed in childhood often will not remember a life without diabetes. In contrast individuals diagnosed with type 2 diabetes will often find a new set of management behaviours required at a time when their lifestyle is already established. In type 1 diabetes micro-vascular and macro-vascular complications are typically a longer-term problem, with avoidance of more acute complications e.g. hypoglycaemia and ketoacidosis of more immediate concern. In contrast avoidance of micro and macrovascular complications may be of more immediate concern to individuals with type 2 diabetes, given that 30% of individuals will have at least one complication when diagnosed, while the acute life- threatening complication of ketoacidosis is not a focus as this is uncommon in type 2 diabetes. In recognition of these differences it is

recommended that type 1 and type 2 populations are examined separately. As has been stated, type 2 diabetes is the more common form of diabetes and is likely to be of increasing burden to the health service, hence it is this population and corresponding literature that are focussed upon in the current thesis.

1.4 Risk Factors for the Development of Type 2 Diabetes

Current understanding of type 2 diabetes has not identified any single causal factor, although a number of risk factors have been identified. These can be categorised as demographic, lifestyle, genetic and clinical and are reviewed briefly below.

1.4.1. Demographic Factors

1.4.1.1 Age - It has been well established that the risk of type 2 diabetes increases with age (see Pickup & Williams, 1997; Venkat Narayan, Boyle, Thompson, Sorensen & Williamson, 2003). Within the UK prevalence at age 45-54 years is 25.8 and 17.4 per 1000 for males and females respectively, rising to 87.2 and 65.5 per 1000 for males and females within the 75-84 years age group (Newnham *et al.*, 2002). This pattern is characteristic of the developed world where the oldest age groups (>65 years) tend to have the largest proportion of individuals diagnosed with diabetes. This is in contrast however to the developing world where the middle age groups of 45-64 years have the highest proportion of individuals with diabetes (Wild *et al.,* 2004). The mechanisms by which age is a risk factor for type 2 diabetes is unclear. Among possible suggestions are the proposition that deterioration of glucose tolerance is a normal facet of aging, alternatively it may be that age interacts with genetic factors to make older individuals more at risk for developing type 2 diabetes (Harris *et al.,* 1995).

1.4.1.2 Ethnicity - Within the UK the prevalence of diabetes is higher in Asian and African Caribbean populations than indigenous Caucasian populations (Raleigh *et al.*, 1996). The prevalence of diabetes increases markedly for a range of ethnic groups whose populations have moved from their countries of origin to more 'westernised' societies such as the USA (Simpson, Shaw & Zimmet, 2003; Abate & Chandalia, 2003) suggesting that lifestyle factors associated with westernised societies could be associated with the development of diabetes. However the differential increases in prevalence between various ethnic groups suggests that ethnicity itself may be related to development of diabetes. Abate & Chandalia, (2003) provide a comprehensive review of this area and suggest several mechanisms to explain the ethnic variations. One possibility is that certain ethnic groups, i.e. Asian populations are more prone to developing abdominal obesity than other groups i.e. African-Caribbean populations. Distribution of fat is an important correlate of development of diabetes with abdominal distribution representing a higher risk. The tendency for abdominal obesity may be genetic, likewise there may be genetic variation in development of insulin resistance and β cell dysfunction which leads certain ethnic groups to have increased risk of type 2 diabetes. It therefore appears likely that both lifestyle and genetic factors play a role in ethnicity as a risk factor for diabetes.

1.4.1.3 Socio-Economic Status (SES) – The role of SES in the development of diabetes is currently unclear with some studies showing no relationship (Eachus, Williams, Chan, Smith, Grainge *et al.*, 1996; Perry, Wannamethee, Walker, Thomson, Whincup *et al.*, 1995) while others indicate that individuals of lower SES have higher prevalence of type 2 diabetes (Meadows, 1995; Evans, Newton, Ruta, MacDonald & Morris, 2000). Although the evidence is not clear for the role of SES as a risk factor for diabetes, a relationship could be expected given the association between lower SES and higher

obesity and poorer health related behaviours which are known to be related to type 2 diabetes (see Whitfield, Clark, Weidner & Anderson, 2002 for an overview of the relationship between SES and health related behaviours).

1.4.2 Lifestyle Factors

1.4.2.1 Obesity - The association between obesity and development of type 2 diabetes has long been recognised and has been demonstrated in both cross-sectional and prospective studies (see Mokdad, Ford, Bowman, Dietz, Vinicor *et al.*, 2003 and Maggio & Pi-Sunyer, 1997 for review of topic). It is estimated that the increased risk of developing diabetes is double if obesity is present (Harris *et al.,* 1995). In addition studies have identified that the duration of obesity is related to the development of diabetes. The risk of obesity has been suggested to be through its association with increased insulin resistance and glucose intolerance and other metabolic abnormalities such as hyperglycaemia, hyperinsulinemia, and dyslipedimia. The extent of association is however greater if fat distribution is around the waist, referred to as visceral or abdominal obesity, as opposed to around the hip and thighs. Although the relationship between obesity and diabetes is strong it should not be thought of as directly causal as not all obese individuals will develop diabetes and not all patients with diabetes are obese, hence as with ethnicity there may be a genetic mechanism through which obesity acts to cause diabetes.

1.4.2.2 Diet – An overview of the role that diet plays in development of diabetes has been given by Simpson *et al.,* (2003) and Franz, Bantle, Beebe, Brunzell & Chiasson *et al.,* (2002). Both reviews report that the association of specific components of the diet to the development of diabetes is unclear with studies reporting conflicting findings, for example some studies suggest a high fat, low carbohydrate diet increases the risk for

development of diabetes while other studies have found no association. Some evidence has been reported that high fibre foods protect against the development of diabetes. In a recent review of the effect of alcohol consumption on diabetes mellitus it was also reported that compared to no alcohol use, moderate alcohol use was associated with a 33% to 56% lower incidence of diabetes, and heavy consumption was associated with a 43% increased incidence of diabetes compared to moderate consumption (Howard, Arnsten & Gourevicth, 2004).

Although the role of specific components of diet in development of diabetes is unclear there is consensus that overall weight loss, commonly by a low fat diet combined with physical activity, is beneficial for preventing type 2 diabetes. The Diabetes Prevention Study (Tuomilehto, Lindstrom, Eriksson, Valle, Hamalainen *et al.*, 2001) and the Diabetes Prevention Program (Knowller, Barrett-Conner, Fowler, Hamman, Lachi *et al.*, 2002), both showed a 58% reduction in the development of diabetes for individuals with impaired glucose tolerance who followed a lifestyle intervention, which comprised dietary and exercise advice.

1.4.2.3 Physical Activity –Lack of physical activity has been reported as an independent risk factor for development of diabetes. Myers, Atwood & Froelicher, (2003) report on a number of studies that have shown an association between physical inactivity and development of type 2 diabetes. In addition prospective studies (see Perry *et al.,* 1995 & Simpson *et al.,* 2003 for overviews) have indicated that risk of diabetes is reduced amongst individuals who take regular moderate exercise. The possible mechanism through which activity prevents development of type 2 diabetes is through both weight loss and the increased insulin sensitivity that physical activity facilitates (Myers *et al.,* 2003).

1.4.2.4 Smoking – Smoking has been presented as a risk factor for the development of diabetes in a comprehensive review of the area (Haire-Joshu, Glasgow, .& Tibbs, 1999). This review reports that several prospective studies have shown smoking to be related to increased risk of developing diabetes. The mechanism suggested is through the increase in insulin resistance that is associated with smoking, and also a difference in distribution of fat, i.e. greater upper body deposits amongst smokers.

1.4.3 Clinical Factors

1.4.3.1 – Impaired Glucose Tolerance (IGT) – This has been described as 'pre-diabetes' and is thought to incur between a 6-10 fold increased risk of developing diabetes (Simpson *et al.,* 2003). It is unclear whether insulin resistance or defects in insulin secretion are the primary problem underlying IGT, however it may be possible that the role of each of these differs for different individuals, and possibly between ethnic groups (Abate & Chandalia, 2003).

IGT is associated with hyperglycaemia, although not at levels high enough to precipitate a diagnosis of diabetes. In some individuals this factor also clusters with dyslipidemia, hypertension, central obesity and microalbuminuria. The presence of two or more of these factors characterizes the metabolic syndrome (World Health Organisation, 1999). It is currently not clear whether the metabolic syndrome is an independent risk factor for development of diabetes above that contributed by insulin resistance, however this possibility has been raised (Alexander, 2003; Meigs, 2003). Future epidemiological and prospective studies and interventions to elucidate the role of the metabolic syndrome have therefore been recommended (Meigs, 2003).

1.4.4 Genetic Factors

The role for genetic factors in the development of diabetes is indicated by the link that family history has in development of diabetes. If an individual has two parents with diabetes the offspring's risk of also developing diabetes is 80%. Where one sibling has diabetes, risk to other siblings is 40% (Harris *et al.,* 1995). Evidence from twin studies also indicates strong genetic influences with concordance in monozygotic twins reported to be between 34-100%, and between 16-40% in dizygotic twins. The association of diabetes in ethnic groups, even within different environmental settings also points to a role for genetics in the development of type 2 diabetes (Simpson *et al.,* 2003). The specific genes that are important in the development of type 2 diabetes are however less clear. Genes that play a role in insulin resistance and obesity have been considered using different methodological approaches such as population association and linkage studies. Currently however no single gene has been found, and it is thought likely that a number of genes are involved. Even if the genes associated with development of diabetes were identified, their interaction with environmental factors such as those described above would mean such issues would still need to be addressed in preventing type 2 diabetes (see Baroni, Leslie, Pozzilli, & Bozzetti, (2000) for more detailed discussion of area).

1.5 The Impact of Type 2 Diabetes

1.5.1 Microvascular Complications

It is well established that there is a strong association between poor blood sugar control and increase in both incidence and severity of microvascular complications (Klein, 1995). The main types of microvascular complications to affect patients with type 2 diabetes are associated with the eyes, kidneys and nervous systems of patients (see

Pickup & Williams, (1997) and Harris *et al.,* (1995) for further information on complications in diabetes).

1.5.1.1 Diabetic Eye Disease - This is the most common of the complications associated with diabetes and affects from 28.8% of those diagnosed for less than 5 years to 77.8% of those diagnosed for 15+ years (Klein, Klein, Moss, Davis & DeMets, 1984). It is primarily the blood vessels of the retina that are affected and hence this complication is often referred to as diabetic retinopathy. This can be broken down into three main forms, background retinopathy, preproliferative retinopathy and proliferative retinopathy. The first two stages are not usually associated with loss of vision but are marked by a degree of ischaemia and haemorrhage in the retinal blood vessels. Although these stages do not always progress onto more serious eye disease their presence does indicate an increased risk for proliferative retinopathy. In this case new blood vessels form, referred to as neovascularization, however because the new vessels are fragile there is a greater risk of major haemorrhage and hence this stage of diabetic eye disease is commonly associated with loss of vision. Vision is also threatened if the macula becomes involved as part of the eye disease (maculopathy). This is a more frequent cause of blindness in type 2 diabetes than proliferative retinopathy, which tends to occur more commonly in younger type 1 patients (Ulbig & Hamilton, 1993). Type 2 diabetes is also associated with an increased rate of development of cataracts, which causes clouding in the lens of the eye and can lead to blindness. Recent developments in laser surgery have however meant that treatment of diabetic eye disease has greatly improved in recent years. Regular check-ups and screening are therefore imperative to ensure that treatment can occur at an early enough stage.

1.5.1.2 Diabetic Nephropathy - Of those patients with diabetic retinopathy two thirds will also suffer from diabetic kidney disease. Again it is the small blood vessels in the organ that are damaged. In nephropathy this results in protein, primarily albumin, leaking from the kidney into the urine. When the degree of protein loss is small (30-300mg/24hrs) this is referred to as microalbuminuria or sometimes incipient nephropathy. Once the protein loss is above 300mg/24hrs this is labelled proteinuria and indicates overt nephropathy. As the extent of proteinuria increases so does loss in glomerular filtration rate, which progresses until end stage renal failure occurs. Once renal failure has occurred patients require either renal transplantation or dialysis to survive. In type 2 diabetes approximately 20-30% of patients develop nephropathy (American Diabetes Association, 1997). The progression of diabetic nephropathy in type 2 patients is linked to both blood glucose and blood pressure control with hypertension associated with greater rates of decrease in renal function once overt nephropathy is indicated. When nephropathy is at the stage of microalbuminuria treatment can be effective. Screening and action at this stage is therefore essential to avoid progression to more serious renal disease. This may be particularly important in different ethnic groups such as Asian patients who show a higher prevalence of all stages of nephropathy compared to Caucasians (Fischbacher, Bhopal, Rutter, Unwin, Marshall *et al.,* 2003)

The presence of microalbuminuria is important not only as an indicator of more serious nephropathy but also because it is an independent risk factor for cardiovascular disease. Commonly it is associated with the presence of hypertension and the combination of these factors leads to a greater risk of cardiovascular disease. This additional risk of microalbuminuria is one reason why early identification and appropriate treatment is considered so important.

1.5.1.3 Diabetic Neuropathy - The term neuropathy refers to damage to the nervous system. Although there are a number of forms of neuropathy associated with diabetes the two forms that are most common are sensorimotor neuropathy and autonomic neuropathy. In both cases the nerves are thought to be either damaged or destroyed by the changes in metabolism caused by hyperglycaemia. Sensorimotor neuropathy most commonly affects the peripheral nerves and is therefore sometimes referred to as peripheral neuropathy. Usually the feet, as the most distal part of the body, are affected first and occurrence tends to be symmetrical. The hands and fingers may also be affected but this tends to be after neuropathy has been present for a number of years. Symptoms such as intense pain or feelings of numbness or 'pins and needles' may be experienced, although some patients will report no sensation in the affected area. Decreased sensation in the feet, together with ischaemia due to atherosclerosis can make a patient at increased risk of developing foot ulcers, which if left unattended, can lead to lower limb amputations. The other main form of neuropathy, autonomic neuropathy, affects the nerves of the autonomic nervous system and hence can have wide ranging effects including sweating upon eating, postural hypotension, diarrhoea and erectile dysfunction affecting as many as 60% of men over 60 with diabetes.

1.5.2 Macrovascular Complications

As the term implies macrovascular complications are related to damage to the body's large blood vessels, predominantly by atherosclerosis. Cardiovascular, cerebrovascular and peripheral arterial disease are the three main forms of this type of complication. Although the association between blood glucose control and progression of complications is less clear for macrovascular disease than it is for microvascular disease, studies such as the UKPDS have indicated that there may be some benefit of

improved glucose control on macrovascular outcomes (UK Prospective Diabetes Study (UKPDS) Group, 1998).

1.5.2.1 Cardiovascular Disease - Atherosclerosis of the cardiac blood vessels can lead to increased risk of both angina and myocardial infarction. The normal symptoms associated with these conditions such as pain and tightness in the chest may not always be present in the person with diabetes making diagnosis potentially more difficult. In myocardial infarction the severity of an attack also tends to be worse than in people without diabetes, which may account for the fact that mortality directly following the MI can be up to 34% in diabetic patients while it is only around 18% in non-diabetic patients. The presence of angina and MI also means there is an increased risk of heart failure. Together these aspects of cardiac disease make it one of the largest risk factors for mortality from diabetes with an estimated 50% of deaths from diabetes primarily related to coronary disease. Relative to individuals without diabetes mortality rates are 2-4 times higher in patients with diabetes.

1.5.2.2 Cerebrovascular Disease - Transient ischaemic attacks (TIAs) may be one of the first indicators that a patient has developed cerebrovascular disease. These are usually the result of emboli that have been released as a result of atherosclerosis in the carotid arteries. Although TIAs tend to have only temporary effects larger ischaemic events can result in strokes leading to permanent neurological damage. Another result of cerebrovascular disease in diabetes can be the development of dementia. This may be caused by ischaemia caused by multiple infarcts, as a result of TIAs or as a consequence of decreased cerebral blood flow stemming from the general atherosclerosis. As with cardiovascular disease patients are at a 2-4 fold increased risk of death following stroke if they have diabetes compared to individuals without diabetes.

Cerebrovascular disease is the second largest cause of mortality in patients with diabetes being responsible for 15% of deaths.

1.5.2.3 Peripheral Arterial Disease - Atherosclerosis of the peripheral arteries tends to occur most frequently in the blood vessels of the legs and feet causing poor circulation and ischaemia. Often the first symptoms associated with this are either gangrenous toes or foot ulcers. These may be precipitated by injury to the foot that has gone unnoticed due to peripheral neuropathy. If not treated promptly foot ulcers and gangrene can lead to lower limb amputations. It is estimated that 50% of patients undergoing amputation have diabetes.

1.5.3 The Psychosocial Impact

1.5.3.1 Quality of Life - An individual's quality of life (QoL) reflects both physical and social functioning together with perceived physical and mental well being (Rubin & Peyrot, 1999). Its importance as a health outcome has been increasingly recognised in management of chronic illnesses (Ewart, 1991) and assessment in studies of diabetes has consequently become more frequent. A number of studies show that individuals with diabetes report poorer QoL than the general population (Wandell, & Tovi, 2000; Hanninen, Takala & Keinanen-Kiukaanniemi, 1998). In comparison to people with some other chronic conditions (e.g. cardiac problems, arthritis, stroke, epilepsy) individuals with type 2 diabetes tend to have a better QoL (see Rubin & Peyrot, 1999 for an overview of this literature).

A consistent finding in the literature is of an association between presence of diabetes, complications and reduced QoL in individuals with type 2 diabetes. Although the majority of studies have been cross-sectional (e.g. Brown, Brown, Sharma, Brown,

Gozum *et al.,* 2000; Wandell & Tovi 2000; UK Prospective Diabetes Study Group, 1999) some studies have looked at the association prospectively (de Visser, Bilo, Groenier, de Visser & Meyboom-de Jong, 2002) giving further weight to the relationship. The association between complications and reduced QoL is so robust that studies that have found other disease characteristics such as duration of diabetes to be correlated with QoL have been accused of not adequately controlling for presence of complications in analyses (Rubin & Peyrot, 1999). A reduction in QoL is also associated with non-diabetic co-morbidity, including both physical (Woodcock, Julious, Kinmonth & Campbell, 2001; Glasgow, Ruggiero, Eakin, Dryfoos & Chobanian, 1997a) and psychological co-morbidities such as depression (Brown *et al.*, 2000; Claiborne & Massaro, 2000; Goldney, Phillips, Fisher & Wilson, 2004).

A further relationship that has been consistently evaluated in type 2 diabetes is that between QoL and glycaemic control. Although not all studies are in agreement, possibly due to measurement techniques (Rubin & Peyrot, 1999), the preponderance of results suggest that better glycaemic control is associated with better QoL (de Visser *et al.,* 2002; Goddijn, Bilo, Feskens, Groenier, Van der Zees *et al.,* 1999; Rubin & Peyrot, 1999). The direction of causality in this relationship is not however clear. It is possible that a reciprocal relationship may be present, but this needs to be elucidated further by comprehensive prospective studies.

As in the general population some demographic characteristics have been shown to be associated with poorer QoL in type 2 diabetes (see Rubin & Peyrot, 1999 for review of studies in both general and diabetes populations). Female gender is associated with lower QoL in type 2 diabetes (Hirsch, Bartholomae & Volmer, 2000; Glasgow *et al.,* 1997a), as is lower SES (Glasgow *et al.,* 1997). In type 2 diabetes older age groups

report more limitations than younger age groups on physical aspects of QoL, but better QoL on social, emotional and mental health functioning than younger age groups (Woodcock *et al.,* 2001; de Visser *et al.,* 2002; Glasgow *et al.,* 1997a).

Studies exploring the associations between QoL in type 2 diabetes and components of the management regimen, e.g. diet, exercise, medication have also been examined, however this literature will be reviewed below under description and impact of individual management components (see section 1.6). In addition the association between QoL and psychosocial constructs such as self-efficacy, social support etc. will be reviewed in chapter 2 where these constructs and their relation to diabetes management as a whole are explored more fully.

1.5.3.2 Depression - As with the reduction in QoL, the risk of clinical depression in individuals with type 2 diabetes is higher than amongst the general population. A meta-analysis conducted by Anderson, Freedland, Clouse & Lustman, (2001) found that the odds of co-morbid clinically relevant depression in individuals with diabetes, is twice that of individuals without diabetes. This odds ratio held when sex, type of diabetes, recruitment method and assessment method were taken into consideration. Similar figures have also been reported in large population studies (Nichols & Brown, 2003; Egede, Zheng & Simpson, 2002). Whether depression is higher amongst individuals with type 2 diabetes compared to individuals with other chronic illnesses is less clear. Some studies report a higher risk among individuals with type 2 diabetes, compared to those with other chronic illnesses (Thomas, Jones, Scarinci & Brantley, 2003), whilst others report no difference (Kessing, Nilsson, Siersma & Anderson, 2003; Weyerer, Hewer, Pfeifer-Kurda & Dilling, 1989).

Prevalence rates of depression for individuals with type 2 diabetes are variable, depending upon the demographic characteristics of samples and methodological characteristics of studies. For example women with type 2 diabetes have higher prevalence rates than men (28% vs 18% respectively) and estimates range from 11% when diagnosis is by standardized interviews, to 31% when self-report scales are used (Anderson *et al.,* 2001). Studies which estimate prevalence rates in small, uncontrolled or restricted samples e.g. in clinic populations may give an unrepresentative picture of true prevalence rates (Anderson *et al.,* 2001). Population based studies are therefore preferable. Recent population based studies have estimated prevalence of diagnosed depression in type 2 diabetes at 17.6% (Nichols & Brown, 2003) or 9.3% for major depressive disorder (Egede & Zheng, 2003). The variation in estimates is influenced by definition of depression and assessment method. Nichols & Brown, (2003), considered any diagnosis of depression or dysthymia as evidence of clinical depression, whilst Egede & Zheng, (2003) only considered major depressive disorders. Diagnostic interviews identify major depressive disorders whilst self-report measures are likely to be sensitive to more minor depressive disorders and may include symptoms that reflect other co-morbid psychiatric illnesses e.g. anxiety disorders. In a large community based study by Pouwer, Beekman, Nijpels, Dekker, Snoek, *et al.,* (2003), it was reported that it was the presence of co-morbid disease with type 2 diabetes that increased the prevalence of depression compared to healthy controls. An association between depression and the presence of diabetes complications has been established previously although the causal directions in the relationship are unclear (De Groot, Anderson, Freedland, Clouse & Lustman, 2001).

The causal relationship between the development of depression and type 2 diabetes is also unclear. One hypothesis is that depression is a risk factor for the development of

type 2 diabetes. A number of prospective studies provide support for this idea (see Talbot & Nouwen, 2000; Arroyo, Hu, Ryan, Kawachi, Colditz, *et al.,* 2004). The relationship could be mediated by a biochemical pathway (see Talbot & Nouwen, 2000 for discussion of this mechanism) or through an impact of depression on risk factors for diabetes e.g. diet, smoking, exercise. In a study reported by Arroyo *et al.,* (2004) behaviours were controlled for in analysis and a moderate increased risk of developing diabetes in individuals depressed at baseline remained, providing support for a biochemical pathway.

The converse hypothesis is that the presence of type 2 diabetes leads to depression. This could be due to biological changes occurring as a result of the development of diabetes, however there is little evidence to support this hypothesis with a number of studies indicating this is unlikely to be the mechanism (Talbot & Nouwen, 2000). For example in a study by Palinkas, Barrett-Connor & Wingard, (1991) depressive symptomatology was assessed in a group of individuals with diabetes, some of whom knew they had diabetes while others did not. Those individuals aware of their diabetes reported 3.7 times higher levels of depressive symptomatology than in those unaware. Rajala, Keinanen-Kiukaanniemi & Kivela, (1997) also reported similar findings from a study conducted in Finland. These studies would suggest that it is the psychosocial demands of being diagnosed with diabetes that influence the relationship between depression and diabetes.

Factors that have been shown to be associated with depression in diabetes include age (Egede & Zheng, 2003; Katon, VonKorff, Ciechanowski, Russo & Lin, 2004), gender (Nichols & Brown, 2003; Katon *et al.,* 2004), educational level (Katon *et al.,* 2004; Egede & Zheng, 2003), longer duration of diabetes (Katon *et al.,* 2004; Palkinkas *et al.* 1991),

presence of complications (De Groot *et al.,* 2001), poor glycaemic control (Lustman, Anderson, Freedland, De Groot, Carney *et al.,* 2000), aspects of the management regimen (see section 1.6 below for more detailed review of this literature), and psychological constructs such as social support, illness beliefs etc (Egede & Zheng, 2003, also see chapter 2 where the literature on psychological constructs and outcomes is reviewed). These factors can be thought to play a mediating role between diabetes and depression, however a lack of prospective studies makes understanding the causal relationships complex, e.g. does depression lead to poor self-management behaviours resulting in poor glycaemic control, or poor glycaemic control lead to lack of motivation for self-management behaviours and depression? Depression in diabetes is associated with development of micro and macrovascular complications (Black, Markides & Ray, 2003), functional disability (Egede & Zheng, 2004; Black *et al.,* 2003), health care utilisation (Egede *et al.* 2002) and poor quality of life (Kohen, Burgess, Catalan & Lant, 1998; Hanninen, Takala & Keinanen-Kiukaanniemi, 1999) the understanding of such relationships is therefore an important area for future research.

1.5.3.3 Anxiety - The literature on anxiety and type 2 diabetes is far more limited than that for depression or QoL. A systematic review of studies in diabetes has however been conducted and shown that anxiety was more frequent amongst individuals with diabetes than the general population (Grigsby, Anderson, Freedland, Clouse & Lustman, 2002). Prevalence rates of 27% for diagnosed anxiety disorder and 40% for raised anxiety symptoms on self-report questionnaires were reported in this review. In addition anxiety was demonstrated to be higher for women than men (55.3% versus 32.9% respectively). These findings are similar to patterns seen for depression, however it is important that the majority of studies included in this review had small sample sizes,

uncontrolled populations and did not distinguish between individuals with type 1 and type 2 diabetes.

Anxiety in individuals with diabetes is associated with poor quality of life (Kohen *et al.,* 1998), however there is little robust evidence of the role of anxiety in other outcomes e.g. development of complications, functioning etc. Again this is an area for future research.

1.6 Traditional Management of Type 2 Diabetes

Given the wide-ranging impact of type 2 diabetes, optimal management has become essential. Traditional management of type 2 diabetes primarily aims to alleviate short-term symptoms and prevent or delay the development of long-term complications. The traditional focus of this has been on control of blood sugar levels, which has long been hypothesised to play a pivotal role in achieving such endpoints. Publication of the United Kingdom Prospective Diabetes Study (UKPDS) has recently provided clear evidence of the importance of blood glucose control in reduction of complications (Stratton, Adler, Neil, Matthews & Manley *et al.,* 2000). This large scale study which followed over 4000 type 2 patients in the UK for over 11 years reported that intensive control of blood sugars with either oral hypoglycaemics or insulin therapy reduces the risk of microvascular complications relative to conventional treatment and shows a positive trend for macrovascular complications (UKPDS Group, 1998a,1998b). Importantly however the study also demonstrated the crucial role that control of blood pressure plays in reducing complications (UKPDS Group, 1998c). For each 10mmHg decrease in systolic blood pressure an associated risk reduction of 12% for any complication related to diabetes, 15% for deaths related to diabetes, 11% for heart attacks and 13% for microvascular complications occurred (Adler, Stratton, Neil, Yudkin, Matthews *et al.,* 2000). Control of

blood pressure is therefore now also considered an essential part of managing type 2 diabetes.

In addition to trying to achieve optimal blood sugar and blood pressure control, management of type 2 diabetes also focuses on managing factors such as obesity, dyslipidaemia, microalbuminuria, smoking and cholesterol levels, which can act as independent risk factors for development of complications. Generally management of these factors compliments management of hyperglycaemia and hypertension and typically a three-tiered approach to treatment is taken. Initial therapy, particularly for overweight and inactive individuals would be lifestyle advice, including diet and activity recommendations, supplemented with oral medication and ultimately insulin therapy as required.

1.6.1 Lifestyle Aspects of Management

1.6.1.1 *Diet* - For the majority of overweight or obese individuals who present with type 2 diabetes, the first recommendation in management is likely to include weight loss. Whether by dramatic approaches such as surgery, use of pharmacological treatments e.g. orlistat or sibutramine, or by more conventional calorie reduction approaches, intentional weight loss appears to have beneficial effects including reduction in mortality (Aucott, Poobalan, Smith, Avenell, Jung *et al.,* 2004; Gregg, Gerzoff, Thompson & Williamson, 2004) and improvement of insulin sensitivity, glycaemic control, hypertension and dyslipidaemia (Klein, Sheard, Pi-Sunyer, Daly, Wyle-Rosett *et al.,* 2004; Wing, 2002). Even moderate weight loss such as 5% of original body weight has been reported to have benefits (Maggio & Pi-Sunyer, 1997).

Although weight loss is important for overweight individuals with diabetes, following appropriate nutritional guidelines has been recommended for all individuals with type 2 diabetes (see Nutrition Subcommittee of the Diabetes Care Advisory Committee of Diabetes UK, (2003) for UK guidelines, and American Diabetes Association, (2003) for USA guidelines). These recommendations specify that for individuals not specifically aiming to lose weight, or with contraindications such as dyslipidaemia or microalbuminuria, a balanced diet comprising approximately 60-70% carbohydrate and monounsaturated fat, 15-20% protein, <10% saturated fat and dietary cholesterol levels <300mg/day is recommended. Typically a diet should aim to be low in fat, high in fibre and include at least five portions of fruit and vegetables per day. There is also evidence that food with a lower rather than higher glycaemic index is beneficial (Brand-Miller, Hayne, Petocz & Colgiuri, 2003). For individuals with dyslipidaemia, or those who are trying to lose weight, lower fat diets and particularly restriction of saturated fats and cholesterol are recommended. For individuals with hypertension modest weight loss and a reduction in sodium intake to 6,000mg salt per day are recommended. Also for individuals with diabetic nephropathy, including those with microalbuminuria, there is some evidence to suggest that a reduction in dietary protein may decrease the progression of the nephropathy (Franz *et al.*, 2002). Dietary approaches may be the first line of management of type 2 diabetes however these recommendations should be maintained even if additional therapies such as oral hypoglycaemics or insulin are required.

It is well accepted that adherence to the dietary guidelines above are important for reduction of complications. The relationship of dietary behaviour to psychological well-being or QoL however, has not been frequently studied in type 2 diabetes, and where present findings are inconsistent. For example frequency of appropriate dietary

behaviour was positively associated with the mental health but not physical or social functioning scales of the SF-20 in a study by Glasgow *et al.,* (1997a). In contrast Watkins, Connell, Fitzgerald, Klem, Hickey *et al.,* (2000) report dietary behaviour to be associated with perceived burden of diabetes such that moderate adherers to diet perceived high burden, but both high and low adherers reported minimal burden (i.e. an inverted U-shaped relationship). In the general population there is a body of literature that suggests that eating patterns are related to mood. For example negative mood is associated with increased food intake (Patel & Schlundt 2001; Steptoe, Lipsey & Wardle, 1998). Such findings have important implications for understanding dietary adherence and are therefore important for the type 2 diabetes population.

1.6.1.2 *Exercise* - As with diet, exercise is a fundamental component of management for the majority of patients with type 2 diabetes (see Sigal, Kenny, Wasserman, Castaneda-Sceppa, 2004 for overview of recommendations). The ideal level and type of exercise recommended for patients with type 2 diabetes is dependent on individual cases and associated complications, however 20-30 minutes moderate exercise on most days of the week is a common target. Consideration of complications including advice on appropriate foot-ware and the possibility of a stress echocardiogram are recommended to avoid exacerbation of any underlying problems. Recommendations however identify physical activity as 'a vital component in the management of type 2 diabetes' (Sigal *et al.,* 2004), and as such encourage the increase of activity even for elderly individuals.

The importance of exercise is related to a range of positive effects for the individual with type 2 diabetes. One of the main benefits is improvement in insulin sensitivity and glycaemic control (Duncan, Perri, Theriaque, Hutson, Eckel *et al.*, 2003; Boule, Haddad, Kenny, Wells & Sigal, 2001; Clark, 1997). The improved glycaemic control that is seen

in individuals, who exercise regularly, has been suggested to be the cumulative result of several exercise sessions rather than actual changes in fitness (Schneider & Ruderman, 1990). However improvement in fitness from exercise is also important given the increased risk of cardiovascular disease in type 2 diabetes. Amongst the general population exercise and improved fitness have been shown to decrease risk of cardiovascular disease (Blair, Kohl, Barlow, Paffenbarger, Gibbons *et al.*, 1995) and the same has been shown for men with type 2 diabetes (Tanasescu, Lietzman, Rimm *et al.*, 2003). In addition many of the risk factors for cardiovascular disease in this population such as hypertension, hyperinsulinemia etc. are associated with insulin resistance, which exercise impacts upon positively (Myers *et al.,* 2003). Exercise also has an established role in assisting both initial weight loss and maintenance of weight loss (Brownell, 1998). Whether exercise can lead to more weight loss from intra-abdominal regions is a further important question given the association of waist to hip circumference to morbidity (American Diabetes Association, 1998).

Exercise has been shown to be associated with improved mood and reaction to stress in the general population (Salmon, 2000). Although the relationship between exercise and mood has not been examined frequently in type 2 diabetes, studies have shown physical activity to be associated with higher QoL (Glasgow *et al.*, 1997a). Watkins *et al.,* (2000) reported a curvilinear relationship between exercise and perceived burden from diabetes, such that high and low exercise levels were associated with higher perceived burden of diabetes than moderate levels of exercise.

1.6.1.3 *Self-Monitoring of Blood Glucose* - Self-monitoring of blood glucose (SMBG) refers to patient performed finger-prick testing of blood glucose, which is recommended by the American Diabetes Association as an important component of care for patients

with type 2 diabetes (American Diabetes Association, 2003). The frequency of monitoring is recommended to be determined on an individual basis and reflective of treatment requirements.

The benefits of SMBG have been debated and reviews of the literature have suggested that the benefits of SMBG in type 2 diabetes are unclear (Coster, Gulliford, Seed, Powrie & Swaminathan, 2000; Faas, Schellevis & Van Eijk, 1997). Some reports have even claimed that SMBG can cause psychological harm and that it is a wasteful use of resources (Gallichan, 1997). Reviews by Coster *et al.,* (2000) and Faas *et al.,* (1997) highlighted the need for large scale studies and RCTs to be conducted to clarify the use of SMBG in type 2 diabetes. Subsequently, a large study of 24,312 adult patients with diabetes demonstrated that regardless of treatment (i.e. diet & exercise, oral hypoglycaemics or insulin therapy) increased frequency of SMBG was associated with improved glycaemic control in type 2 diabetes (Karter, Ackerson, Darbinian, D'Agostino, Ferrara *et al.*, 2001). Murata, Shah, Hoffman, Wendel, Adam *et al.,* (2003) also reported intensified SMBG (4 times daily) to be associated with improvements in glycaemic control, although this was dependent on strong compliance to the protocol. Franciosi, Pellegrini, De Berardis, Belfiglio, Cavaliere *et al.,* (2001) found SMBG to be associated with better metabolic control but only amongst insulin treated individuals who were able to make adjustments to their insulin therapy. The adjustment of life-style behaviours in response to SMBG may be key to its efficacy. In a RCT reported by Schwedes, Siebolds & Mertes, (2002), SMBG taught in conjunction with a self-regulation intervention, demonstrated significant benefits relative to a control group for glycaemic control. A further study by Bjorsness, Kerzowski, Harwell, McDowall, Butcher *et al.,* (2003) explored peoples' understanding of their SMBG results and the actions they took in response to these, and found that a high proportion of individuals neither knew their

target blood glucose level nor took action in response to SMBG readings. It may be that SMBG alone is not beneficial, but when included as a component of a more inclusive lifestyle approach where individuals are taught how to make use of SMBG to facilitate lifestyle changes, benefits will be observed (Faas *et al.,*1997). An examination of patients' perceptions of SMBG also suggests that it is when SMBG is combined with education that benefits are perceived (Peel, Parry, Douglas & Lawton, 2004).

Studies exploring the association between SMBG and QoL have shown a positive association in one study using the SF-20 (Glasgow *et al.,* 1997a) but no association in another (Hanninen, Takala & Keinanen-Kiukaanniemi, 2001). When well being is considered, one study has shown that for individuals not treated with insulin, SMBG more than once per day is associated with higher levels of distress, worry and depressive symptoms than less frequent testing (Franciosi *et al.*, 2001). Another study however reported no association between frequency of SMBG and well being (Wredling, Stalhammar, Adamson, Berne, Larsson *et al.*, 1995), whilst a study teaching SMBG combined with education on how to use results improved general well being and depression (Schwedes *et al.*, 2002). The relationship between SMBG and QoL or well being and mediating factors is therefore not clear at present.

1.6.1.4 *Smoking* - In diabetes the recommendation is not to smoke. This is considered particularly important for patients with type 2 diabetes, for a variety of reasons. Smoking has been associated with increased insulin resistance (Targher, Alberiche, Zenere, Bonadonna, Muggeo *et al.*, 1997) and greater upper body fat distribution, which can influence insulin sensitivity (Chan, Rimm, Colditz, Stampfer, Willett, 1994, Gunton, Davies, Wilmshurst, Fulcher & McElduff, 2002). Smoking cessation has therefore a potential role in improvement of glycaemic control. The more familiar concern about

smoking and diabetes is perhaps the added risk presented for microvascular complications such as nephropathy and neuropathy. For macrovascular complications the risk of stroke and cardiovascular disease are also increased with smoking. Smoking cessation is therefore a primary recommendation to patients who smoke, however even reduced smoking may be of benefit (Glasgow, Toobert, Riddle, Donnelly, Mitchell *et al.*, 1989). Some patients report concern about weight gain after giving up smoking. The evidence suggests however that the risks associated with continuing smoking outweigh those from weight gain (Haire-Joshu, Glasgow, & Tibbs, 1999). Smoking has also been associated with depression although the direction of causality in this relationship is not clear (Katon *et al.*, 2004; Egede & Zheng, 2003)

1.6.1.4 *Additional Management Behaviours* - Although diet, exercise, SMBG and not smoking are the most frequently discussed lifestyle behaviours in type 2 diabetes a range of other behaviours are also important for optimal management. These behaviours include foot-care behaviours, such as checking feet regularly to ensure damage does not go unnoticed; wearing or carrying diabetes identification, which is particularly important for those individuals at risk of hypoglycaemia; and frequent attendance at clinic visits or screening appointments for early detection of complications. Although these behaviours are important components of care for the individual with type 2 diabetes they are not reviewed here as relatively little research has evaluated their specific associations with outcomes.

1.6.2 Pharmacological Aspects of Management

1.6.2.1 *Oral Hypoglycaemics* - Although hyperglycaemia may initially be controlled by lifestyle management, given the progressive nature of type 2 diabetes, it is likely that most patients will ultimately require pharmacological intervention. A range of oral

hypoglycaemics are available for this purpose and act through varying mechanisms (see BMA, 2004; Willett & Albright, 2004; Inzucchi, 2002 and Clark, 1998 for overviews). One of the most commonly used drugs, particularly with overweight patients, is metformin, from the class of biguanides. This acts by reducing insulin resistance and has its main influence by decreasing production of glucose from the liver. Benefits of metformin are that it is associated with either decreases or no change in weight, it is not associated with increased insulin levels or hypoglycaemia, and it may decrease detrimental lipid levels. In addition although some patients may experience gastrointestinal complaints this is commonly not severe. Thiazolidinediones, also referred to as glitazones and including pioglitazone and rosiglitazone, are a second class of drug that act by decreasing insulin resistance in peripheral tissues. These agents have shown preservation of the β cells of the pancreas, hence endogenous insulin deficiency is prevented and the need for insulin therapy delayed. In addition the thiazolidinediones have benefits on lipoproteins, which lead to an increase in high-density lipoprotein and decrease in low-density lipoproteins. This class of drugs has however been associated with some side effects such as weight gain, oedema, and a need to monitor liver function. In addition the long term benefits of thiazolidinediones has yet to be demonstrated (BMA, 2004).

Some hypoglycaemic agents use a different mode of action i.e. stimulation of insulin secretion. The sulphonylureas, including long acting such as glibenclamide and shorter-acting such as gliclazide glimepiride,and tolbutamide, are the most established group with this action and act on the β cells of the pancreas. They have demonstrated benefits on hyperglycaemia and reducing microvascular complications. They have, however, been associated with hypoglycaemia, weight gain and possibly hyperinsulinemia which

may have additional cardiovascular risks. The shorter-acting sulphonylureas are however associated with less hypoglycaemia.

Non-sulphonylurea secretagogues such as repaglinide and nateglinide also stimulate insulin secretion. This later group have a short half-life and rapid onset of action, which results in a greater impact on postprandial glucose excursions and less risk of hypoglycaemia. Repaglinide can be used as a monotherapy for individuals who are not overweight, however nateglinide should only be used in combination with metformin.

A further group of oral hypoglycaemics known as α glucosidase inhibitors, e.g. acarbose, act by inhibiting the breakdown of complex carbohydrates into monosaccharides. Unfortunately these drugs are often associated with gastrointestinal complaints that lead to many patients discontinuing the therapy (Inzucchi, 2002). Use of any of the above drugs tends to begin with monotherapy and subsequently progresses to combined therapy as glycaemic control deteriorates.

1.6.2.2 Insulin Therapy - If the patient's blood glucose cannot be well controlled even with combined oral hypoglycaemic therapy it is likely that insulin treatment will be initiated. One of three major regimens is usually selected (see BMA, 2004; Pickup & Williams, 1997 chapter 38 for an overview). Twice daily injections of premixed short and intermediate acting insulin is often recommended with injections administered before breakfast and dinner. Alternatively multiple injections of short acting insulin before meals and intermediate acting insulin at bedtime may be used. This latter regimen may be less common however because of patients reluctance for frequent injections and fear of weight gain. The third alternative is for a combination of insulin and oral hypoglycaemics, which may be particularly appropriate for patients who can only tolerate

one insulin injection a day. Insulin glargine is a recently introduced analogue with prolonged action, given only once daily. This is suitable for individuals who would otherwise need twice daily insulin injections in combination with oral hypoglycaemics (BMA, 2004).

1.6.2.3 Anti-Hypertensives - Although diet, exercise and smoking cessation play a role in managing hypertension, for patients with blood pressures of >140/90mmHg the addition of drug therapy is indicated. The target blood pressure in diabetes is <130/80mmHg (Arauz-Pacheco, Parrott & Raskin, 2002). If an individual present with microalbumniuria or they are over 55 with cardiovascular risk factors, the tablet of choice is an angiotensin converting enzyme (ACE) inhibitor, as these have been associated with reduced cardiovascular events. Several other categories of drugs such as β blockers, diuretics, angiotensin receptor blockers (ARBs) etc. have also shown efficacy and selection should be based on individual patient characteristics, with many patients requiring combined therapy.

1.6.2.4 Treatment of Dyslipidemia - Abnormalities in lipid levels, possibly as part of the metabolic syndrome, are common in type 2 diabetes and have implications for increased risk of cardiovascular disease (American Diabetes Association, 2002). Management of dyslipidemia is therefore important and aims to decrease low density lipoprotein (LDL) cholesterol, increase high density lipoprotein (HDL) cholesterol, and lower triglycerides. Diet and exercise play a role in achieving these objectives but pharmacological agents are an important adjunct. The groups of medications which can be used are statins (HMG CoZ reductase inhibitors), fibric acid derivates, which lower LDL cholesterol and triglycerides, and fibrates and niacin which increase HDL cholesterol. Initiation of statins

is usually first line therapy, however combination therapy may be necessary for individuals with combined hyperlipidemia.

1.6.2.5 *Anti-platelet agents* - Aspirin is an anti-platelet agent that has been recommended for individuals with type 2 diabetes and one or more cardiovascular risk factors (American Diabetes Association, 2003). This is recommended as a result of several large studies and meta-analysis, which indicate aspirin to be associated with a decrease in risk for MI of approximately 30% and strokes by 20%.

The pharmacological agents discussed above have benefits in reducing long-term complications, however their impact on QoL and psychological well-being is also important. The most consistent finding is that individuals treated with insulin have a higher risk for major depression (Katon *et al.,* 2004) and poorer QoL than individuals treated either with just oral hypoglycaemics or diet and exercise (Katon *et al.,* 2004, Hirsch *et al.,* 2000). In the UKPDS trial the impact of intensive medication policies on QoL was examined and it was reported that individuals using insulin and experiencing 2 or more hypoglycaemic episodes had lower quality of life as reflected by mood disturbance, tension and less work satisfaction (UKPDS Group, 1999). This suggests that it may be the increased risk of hypoglycaemia that relates insulin to reduced QoL, however in a study by Goddijn, Bilo, Feskens, Groenier, Van der Zees *et al.,* (1999) reduced QoL remained even when hypoglycaemic events were controlled for. Further exploration of these relationships may therefore be beneficial.

1.7 Difficulties in Following the Management Regimen

It is clear that the regimen required for successful management of type 2 diabetes is both complex and demanding. It must also be maintained on an ongoing and daily basis.

Each of these characteristics, i.e. complexity, length and intensity of a regimen have been associated with poor adherence, across a range of medical conditions (Haynes, Taylor & Sackett, 1979). It should therefore not be surprising that many patients with type 2 diabetes report difficulty in managing their condition. It is commonly reported that individuals have greatest difficulty following lifestyle recommendations e.g. diet or exercise, however more medical components of the regimen e.g. taking medication or SMBG are also associated with some non-adherence (Ruggiero, Glasgow, Dryfoos, Rossi, Prochaska *et al.*, 1997; Ary, Toobert, Wilson & Glasgow, 1986).

Studies reporting levels of non-adherence per se have been less frequent than those looking at correlates of non-adherence (Glasgow, 1991), however a limited number of studies have been reported for each of the self-management behaviours. A large survey (NHANES III) of individuals with type 2 diabetes conducted in the USA assessed adherence to dietary guidelines and reported that 62% of individuals ate less than 5 servings of fruit or vegetables a day, and almost two thirds of respondents derived more than 30% of their calories from fat with greater than 10% from saturated fat (Nelson, Reiber & Boyko, 2002). Ruggiero *et al.,* (1997) also reported that approximately 36% of individuals followed their dietary plan only sometimes, rarely or never.

For exercise behaviour two studies in the late 1990s reported that more than 50% of individuals with type 2 diabetes were not participating in any physical activity (Hays & Clark, 1999; Ford and Herman, 1995). In the NHANES III survey a slight improvement was seen with 31% of respondents reporting no physical activity, however an additional 38% were still reported to be taking less exercise than recommended (Nelson *et al.*, 2002).

Adherence to SMBG was explored in a study by Vincze, Barner, Lopez, (2004) and reported only one third of individuals as adherent. In a large-scale study of 41,363 patients with type 2 diabetes 67% of respondents reported SMBG less frequently than recommended (Karter *et al.*, 2000). For individuals with type 2 diabetes treated with insulin only 17% were found to have obtained enough testing strips to test daily as recommended (Evans, Newton, Ruta, MacDonald, Stevenson *et al.*, 1999).

Adherence to medications for diabetes has been the topic of a recent systematic review (Cramer, 2004). This review reports that adherence to OHA ranges from 36-93% when retrospective data is used, from 61-85% when prospective studies were employed and 63% for insulin use amongst type 2 individuals. The more regular the daily regimen of medication use, e.g. three times daily versus once daily, the poorer the rate of adherence. In addition the longer the time period that individuals had been prescribed medication the poorer adherence. It is clear that even though medication taking is often thought of as one of the better adhered to components of the diabetes regimen patients still find this difficult. If the prevalence of non-adherence to medication is not understood there is a risk of increasing medication dosage or frequency unnecessarily (Cramer, 2004).

It is apparent that adherence to almost all aspects of the diabetes regimen is less than desirable, however it is not the case that individuals can be categorised as either adherent or non-adherent. There is now considerable evidence to suggest that adherence to different aspects of the regimen are not strongly related (Ary *et al.,* 1986; Glasgow *et al.,* 1989). In the study by Glasgow *et al.,* (1989) correlations between self-care behaviours ranged between r=–0.18 to r=0.31 with a mean of r=0.06. Assessment of behaviours should therefore be made and reported individually.

1.8 From Adherence to Self-Management

The concept of non-adherence, like that of compliance, is derived from an approach where the health-care professional is seen as having primary responsibility for a patient's care, which is in line with a biomedical model of health care. In the last decade however the appropriateness of this approach for individuals with chronic illness has been challenged. It has become recognised that rather than the health care professional, responsibility for diabetes management lies with the individual with the condition (Glasgow & Anderson, 1999). This is because it is the individual with the chronic illness who can, and does, make the choices of what behaviours they are to carry out on a day-to-day basis. This may or may not be in line with recommendations from health care professionals. It is also the person with diabetes who has to live with the consequences of their choices, such as the development of complications or change in lifestyle.

Recognition of the individual's responsibility for managing their condition requires a change in relationship between health care professional and patient to a collaborative one where both are equal partners in care. The health care professional's role is to work together with the patient to help them make informed choices about their condition and learn effective skills for 'self-management'. Self-management has been defined by Barlow , Wright, Sheasby, Turner & Hainsworth, (2002) as:

> "... the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition. Efficacious self-management encompasses ability to monitor one's condition and to effect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life. Thus a dynamic and continuous process of self-regulation is established."

As this definition highlights self-management is much more than simply adhering to health care professionals' advice on behaviour change. It requires informed decision making and management of the social and emotional consequences of the condition. In diabetes considerable work in support of a self-management approach has been conducted by Glasgow and colleagues, who have examined both factors related to self-management and interventions to improve self-management (for an overview see Glasgow, Toobert, Hampson & Wilson *et al.,* 1995; Glasgow, Hiss, Anderson, Friedman, Hayward *et al.,* 2001). A second body of work that is complementary to the concept of self-management is the empowerment approach (Feste & Anderson 1995; Anderson, 1995). Four pillars of empowerment are described, awareness, freedom, choice and responsibility. Again the emphasis is on the individual with diabetes taking responsibility for their condition but with help from the health care professional to facilitate empowerment. Both these bodies of work have highlighted that management of type 2 diabetes requires more than simple following of instructions. In the next chapter the current understanding of factors associated with self-management in type 2 diabetes are presented, before a review of self-management interventions is given in chapter three.

CHAPTER TWO: SELF-MANAGEMENT OF TYPE 2 DIABETES

2.1 Structure of the Chapter

This chapter explores constructs that have been shown to be associated with self-management outcomes in type 2 diabetes including behaviours, clinical and psychosocial outcomes. The chapter begins with the presentation of six key theories from Health Psychology that describe rationales of how psychosocial constructs influence self-management outcomes. Studies that have examined the association of such constructs with self-management outcomes in type 2 diabetes are then reported. Finally the implications of this research for diabetes management and interventions designed to improve management of type 2 diabetes are discussed.

2.2 Health Psychology Theories

Chapter one reported that management of type 2 diabetes requires individuals to carry out a number of behaviours such as implementing an appropriate diet and exercise regimen, monitoring blood glucose levels and taking medications. It is argued that by conducting such behaviours, control of diabetes will be improved, with implications for both clinical (for example reduced micro and macrovascular complications) and psychosocial (improved QoL, psychological well-being) outcomes. Current research however suggests that performance of behaviours and subsequent outcomes in diabetes are not optimal. A greater understanding of what factors influence both behaviour change and outcomes such as glycaemic control, QoL and psychological well-being may therefore be helpful in identifying how to improve self-management in type 2 diabetes.

Within Health Psychology a number of theories have been developed to explain behaviour change and its consequent outcomes. These theories primarily address

how an individual's social and cognitive worlds influence behaviour and adjustment to illness, and hence are called social cognition theories. Examples of such theories include the Health Belief Model (Becker, 1974; Janz & Becker, 1984), The Theory of Planned Behaviour (Ajzen, 1985, 1991), Social Cognitive Theory (Bandura, 1977, 1986), Self-Regulation Theory (Leventhal, Nerenz & Steele, 1984), the Transtheoretical Model (Prochaska & DiClemente, 1984; Prochaska, DiClemente & Norcross, 1992), the Model of Action Phases (Heckhausen 1991; Gollwitzer 1990,1993), the Stress Coping Model (Lazarus & Folkman, 1984). Overviews of such health psychology models are provided in most introductory textbooks, however a selection of these theories are presented below to illustrate some of the key constructs that have been identified in these theories. The theories presented are those that are considered to be most relevant to management of chronic disease and in particular type 2 diabetes. The theories are not discussed exhaustively as this is beyond the scope of the thesis.

2.2.1 Social Cognitive Theory (SCT)

SCT (Bandura, 1977, 1986, 1997) has become one of the most influential social cognition models in the field of self-management. Central to this theory is the concept of expectancies, which are described in three main forms, i) situation-outcome expectancies, ii) outcome expectancies and iii) self-efficacy expectancies. The first of these, situation-outcome expectancies, relates to ones expectations over what will occur if life continues as present and no behaviour change is made, for example 'what are the implications of not taking medication?'

The second set of expectancies, outcome expectancies (OEs), are cognitions which relate to what the outcome of any given behaviour is expected to be. OEs can be separated into expectancies about physical, social and self-evaluative outcomes. Physical OEs are expectations about what the perceived sensory impact of a

behaviour is likely to be, for example whether pleasant or unpleasant. Also included are perceptions about the severity of an illness and susceptibility of an individual to disease (these are similar to concepts described by Becker, (1974) in the health belief model). Social OEs are expectations about how other people will react to a behaviour and the consequences within ones social world. Individuals are therefore said to make judgements by considering whether the outcome of a behaviour will adhere to or violate social norms. It would be expected that adhering to social norms would produce positive results while acting against them would bring negative results. Finally self-evaluative OEs refer to an individual's judgement of whether a behaviour would meet their own standards. This is an important influence on subsequent behaviour. For all types of OEs both positive and negative implications are evaluated, these act as incentives or disincentives to the behaviour respectively.

The third set of expectancies described in the SCT are efficacy expectations, commonly referred to as self-efficacy, which relates to an individual's perception of the degree to which they are capable of performing a given behaviour. There are three elements to self-efficacy for any specific behaviour; magnitude which describes an individual's perceived efficacy for their most capable performance, strength which refers to their confidence in their assessment of magnitude, and generality which refers to whether this sense of efficacy translates to different situations, for example is self-efficacy for consuming a low fat diet the same at home as it is at work? It is important to note that self-efficacy in this theoretical approach is conceptualised as specific to individual behaviours rather than as a generic trait-like construct.

SCT also describes how self-efficacy beliefs are shaped, which is important for the development of interventions targeting behaviour change. The first mechanism described is mastery, which involves the individual attempting the behaviour in question. Success leads to increased efficacy while failure leads to decreased

efficacy. The strongest and most robust sense of efficacy is said to be achieved not when success is immediate but when an individual overcomes obstacles, as this increases resilience to failure. Vicarious experience is the second way in which self-efficacy is influenced and is primarily via modelling of a behaviour. This is likely to be most successful when someone who the individual can identify with models the behaviour. A third influence is social persuasion, for example when a teacher persuades a student of their abilities, possibly by highlighting past successes and helping them to avoid failures. Finally attention and management of emotional reactions can help increase self-efficacy. When an individual is in a negative mood self-efficacy will be evaluated less positively. Stress may also make an individual attune to and interpret physiological sensations as negative although they may be normal reactions for example to exercise. Self-efficacy can therefore be increased by helping to improve mood, decrease stress levels and by making people aware of how emotional state influences their perceptions.

As with all social cognition models demographic and contextual variables are acknowledged as important influences on beliefs in SCT, but are thought to have a more distal role, and hence are not explicitly incorporated within the model.

2.2.2. The Self-Regulation Model (SRM)

The SRM (Leventhal, 1984) is essentially a feedback model depicting how an individual's cognitive and emotional representations of an illness influence coping procedures and subsequent appraisals of these actions. The model is said to be a parallel response model as two parallel pathways are depicted, one related to cognitive representations and pathways and the second related to emotional representations and pathways. The concept of illness representations is a central part of the SRM and refers to the 'common-sense' picture of an illness that an individual holds within their head. A number of studies examining the content of

illness representations have been completed and summarised by Leventhal, Benyamini, Brownlee, Diefenbach, Leventhal *et al.,* (1997). These studies suggest that there are five main components of illness representations. The first is termed identity and relates to the symptoms or label that an illness is given. Time-line is another key component of illness representations and relates to beliefs about how long the illness will last e.g. whether it is an acute, chronic or cyclical condition. Consequences, causes and cure if an acute illness or control of a chronic illness are the other main aspects of illness representations and are largely self-explanatory. Each of the five components can be related to both the cognitive and emotional processing of illness information and are said to influence choice of coping procedures, which influences outcomes. The final step in the model is the appraisal and evaluation of outcomes, which in turn may feed back and lead to an alteration in the illness representation or change in coping procedures, hence the label SRM. How an individual copes with an illness and the behaviours that are followed are hypothesised to influence clinical and psychosocial outcomes. An important component of this model is its attempt to incorporate cultural and social context. Leventhal *et al.,* (1997) have described how such influences have an important impact on the content of each belief for example the belief that stress is a risk factor for development of various health problems may vary throughout the world.

2.2.3 The TransTheoretical Model (TTM)

The TTM (Prochaska & DiClemente, 1984; Prochaska, DiClemente & Norcross, 1992) is one of a number of stage models that have been developed to explain behaviour change. Others include the Precaution Adoption Process Model (Weinstein, 1988), however this has been evaluated less frequently than the TTM. Unlike models that conceive of behaviour change as a continuum between motivation and action, stage models propose a number of defined stages through which behaviour change is said to occur. In the TTM five stages of change are

described and labelled readiness to change (RTC). Precontemplation is a stage when no behaviour change is being made, and none is planned for within at least the next 6 months. Contemplation is when an individual is beginning to consider taking action and intends to do so within the next 6 months. Preparation is when a firm intention to carry out a behaviour has been made, and action is planned for within the next month. Action is the point when the behaviour is being performed, or has been performed within the last 6 months. Finally maintenance is the point where people have been performing a behaviour, or taking action, for longer than 6 months and it is being maintained without relapsing. An additional stage, termination, is sometimes described where the behaviour is no longer vulnerable to relapse and the individual has absolute self-efficacy in all situations. For lifestyle changes it is unlikely that many people will achieve termination, as such behaviours are particularly vulnerable to emotional and social influences and hence relapse. Although describing a temporal series of stages the TTM predicts that people will spiral between stages e.g. go from action to preparation or contemplation through to action again before reaching maintenance of the behaviour.

The five stages are the most frequently referred to aspect of the TTM, however they are only one of the proposed constructs. Ten processes of change are also described which are said to assist an individual in progressing through the stages. Five of these are fundamentally cognitive or experiential processes and drawn from the field of psychotherapy. These include consciousness-raising, dramatic relief, self-re-evaluation, environmental re-evaluation and self-liberation. These processes are thought to be used more in the early stages of the model. The processes used more in the later stages when action is occurring are more behavioural and drawn from the literature on behaviour therapy. Included are social liberation, counter-conditioning, stimulus control, contingency management and helping relationships. Although certain processes may be more frequently used at specific stages precise

ties between processes and stages are not well defined in the model and may vary between individuals.

A further construct described in the TTM is decisional balance. This is essentially the 'weighing up' of the pros and cons of performing the behaviour. In a review of studies looking at 12 different behaviours it was consistently seen that in pre-contemplation cons were higher than pros, however cross-over tended to occur between pre-contemplation and action so that by action and maintenance pros were rated higher than cons (Prochaska, 1994). Based on these findings it has been suggested that when people are in pre-contemplation the target should be elucidating the pros of behaviour, transferring to managing the cons of behaviour when people reach contemplation (Prochaska, 1994). Additional constructs including self-efficacy and temptation, occurring from negative affect and positive social situations and craving, are also described as influencing progress through the stages.

The implications of the TTM for behaviour change is that interventions should be stage matched. It is argued that it is inappropriate to direct action oriented interventions at individuals who are at pre-contemplation or contemplation, which is the approach that many health education interventions have taken. Rossi, (1992) reported that across 15 behaviours approximately 40% of individuals were at the stage of pre-contemplation, 40% in contemplation and 20% in preparation. A number of studies have been reported which demonstrate greater efficacy for stage-matched interventions than action focussed interventions relative to controls (Prochaska, Johnson & Lee, 1998). However in some smoking cessation interventions this has not been the case (Sutton, 2000).

The TTM has also been open to a number of criticisms (see for example Bandura, 2000; Sutton, 2000). Amongst those raised are that stages are defined in terms of time periods without necessarily change in behaviour and transformational changes; stages are said to be artificial segments of a continuum yet rather than moving between stages individuals could be seen as fluctuating in their control over behaviour (Bandura, 2000). It has been argued that the TTM is not sufficiently defined and does not provide a clear enough description of how the various constructs relate to stages and what the causal relationships are between constructs (Sutton, 2000), which limits the extent that stage matched interventions can be developed. Although such criticisms indicate the limitations of the TTM, De Vries *et al.,* (2000) have argued that the development of stage models have at least served to highlight the importance of regarding behaviour change as a process rather than as a dichotomy, and indicated that different individuals may be receptive to different forms of intervention.

2.2.4 The Model of Action Phases

In a similar way to the TTM the Model of Action Phases (Heckhausen, 1991; Gollwitzer, 1990,1993) focuses on different stages of behavioural action. It proposes four temporal phases that transcend the process of deciding to act, through to completion of action. The first stage defined as pre-decisional involves a weighing up of wishes. It is argued (Gollwitzer & Oettingen, 2000) that most people have more wishes and desires to follow than is possible to pursue and that wishes are not always complementary. A preference of which wishes should be followed therefore involves a decision said to be based on feasibility and desirability. Feasibility is conceptually similar to perceived behavioural control as it relates to the likelihood of a wish being realised based on perceived skills, barriers etc. Desirability is conceptually similar to outcome expectancies as it concerns expected value and positive and negative consequences of the behaviour. Having decided on a

preference between wishes the next phase in the model is development of a commitment to act on the wish, this can be conceived of as a goal intention. This stage is prior to action on the goal and is referred to as the pre-action phase. The likelihood of progress from the pre-action to subsequent action phase can be enhanced if implementation intentions are developed. Implementation intentions are the specific plans of how the goal intentions are to be carried out, and include details on when, how and where the action is to take place. A situation cue can then be linked to the behaviour to increase the likelihood of the behaviour being performed when the specific situation cue becomes available. Gollwitzer and Oettingen, (2000) describe a number of studies, including some examining health behaviours, which describe how implementation intentions increase the likelihood of a behaviour being performed. It is also suggested that by developing an implementation intention an implementation mindset is formed which again increases the likelihood of goal intentions being translated to action. Implementation intentions and an implementation mindset are also described as assisting the action phase of the model where the objective is to complete the goal successfully. The explanation for this is that often when a behaviour is performed barriers will be present. If when developing implementation intentions these are considered and planned for then they will be coped with more successfully, and increased perseverance will be exerted than if such planning was not completed. Finally the last stage of the model is post-action and involves evaluating the performance of the behaviour and comparing it to what had been desired. This forms a self-regulatory process whereby the person will either continue or discontinue with the goal.

2.2.5 The Stress-Coping Model

The focus of the stress coping model of Lazarus & Folkman, (1984) is on how an individual responds to and manages challenging situations. Such situations are evaluated for firstly the demands that they place on the individual, and secondly the

resources the individual believes they have for coping with that demand. Where demand is perceived to exceed resources to cope with the situation it is said to be stressful. Within this model it is an individual's perception of demand and resources that are important rather than the objective, or any other assessment of the situation. Hence two individuals with objectively the same demand and coping resources may differ in their judgement of stress for any given situation.

Lazarus and Folkman, (1984) describe the weighing up of demands and resources in terms of primary and secondary appraisal. Primary appraisal is the general assessment of any given situation. Situations are said to be perceived as either irrelevant and hence cause no concern, beneficial with positive outcomes anticipated, or stressful when a potential negative outcome is anticipated. Where a situation is perceived as stressful it is further evaluated in terms of the harm or loss that has already occurred for the individual, threat which is the harm that may occur in the future, and challenge which refers to the possibility for positive outcomes to occur from dealing with the stress, for example through mastery of the situation or from learning new skills. The higher the perception of threat and lower the perception of challenge the more stressful a situation is likely to be perceived.

Secondary appraisal reflects the assessment of resources to cope with the situation and is likely to be influenced by prior experience of managing similar situations. Coping strategies are then put in place to attempt to manage the situation. Common coping strategies for managing stressful situations have been categorised as either problem or emotion focussed coping strategies. Problem focussed coping aims to actively manage the situation and includes things such as information gathering or problem solving. Emotion focussed coping aims to regulate the emotional response to the situation e.g. denial, positive reappraisal, avoidance. The benefit of any coping strategy is largely dependent on the situation, although it has been argued

that active coping strategies, whether problem or emotion focussed tend to be more beneficial than passive-avoidant strategies (De Ridder & Schreurs, 1996).

Although the terms primary and secondary appraisal imply a consecutive process, in reality such appraisals are interdependent. The appraisal of a situation as stressful is also influenced by both individual differences, and characteristics of the situation. Individual differences include personality variables and characteristics such as self-esteem with individuals higher in self-esteem likely to perceive less threat and stress from a variety of situations (Sarafino, 1998). Characteristics of the situation include whether the demand is imminent, ambiguous, undesirable or uncontrollable, with such factors likely to precipitate higher perceived stress. For each of these characteristics again it is the individual's perception that will influence whether the situation is judged as stressful.

2.2.6 Social Support

Although not a social cognitive theory in the sense of positing the relationship between several constructs and outcomes, social support is a concept that has come to be measured frequently in psychosocial research (McNally & Newman 1999), and plays an important role in our understanding of health behaviours and subsequent outcomes. Social support has been conceptualised and measured in a variety of ways including structural and functional approaches as described by Schwarzer & Leppin, (1991) and Keeling, Price, Jones & Harding, (1996). Structural approaches are perhaps the more objective and refer to how socially integrated an individual is in terms of size of social network and the relationships which are represented. In contrast functional approaches relate to two areas i) cognitive aspects of support, which is the perceived support available and ii) the actual support received, referred to as behavioural support. An individual can vary in the extent that they are satisfied

with both perceived and received support, which can be an important influence on the effectiveness of support (Keeling *et al.*, 1996).

Two mechanisms have been hypothesised through which social support affects health outcomes (Cohen & Wills, 1985). The first is termed the 'Buffer Theory' and hypothesises that the effect of social support on health is dependent upon the level of stress experienced. At low levels of stress social support does not have an influence on health outcomes, however at high levels of stress individuals with greater social support are protected against some of the detrimental health outcomes associated with stress. The mechanism of action for the buffer theory has been suggested to be through an individual's appraisal of stress i.e. an individual with high social support will perceive they have better resources to meet the demands of the situation hence will perceive the situation as less stressful. This is in line with the concept of secondary appraisal in Lazarus and Folkman's Stress-Coping Theory (1984). Alternatively it has been suggested that although the individual may perceive a situation as stressful social support will aid coping with the stress by offering alternative perspectives for problem solving or cognitive restructuring.

In the 'Main Effects Theory' it is suggested that regardless of stress level high social support will have a protective effect on health. One mechanism for this is that people with high support may engage in more healthful lifestyles out of a desire to keep themselves healthy because of their sense that others care and need them. In addition individuals higher in social support may have a greater sense of stability and self-esteem, which may lead to a more positive outlook on life.

Support for each of these models appears dependent on the conceptualisation of social support used, with structural measures of social integration supportive of Main

Effect Theory, whilst measures of perceived availability of support are more supportive of the Buffer Theory (Cohen & Wills, 1985).

Although social support is generally considered to have positive associations with health outcomes it has also been acknowledged that there may be some negative effects as well (McNally & Newman 1999; Gallant, 2003). Negative effects may stem from meeting demands that are required from a social network, or from behaviours that are perceived as unhelpful e.g. nagging, over protection, unhelpful advice etc (Gallant, 2003). Social support can perhaps then be described as 'a double edged sword' with benefits potentially dependent on the communication skills of the individuals giving and receiving support.

2.3 Predictors of Self-Management Outcomes in Type 2 Diabetes

The above theories present a number of constructs that are posited to predict behaviours and other outcomes important in self-management. The extent that these constructs, as well as background variables such as demographic factors, have been explored in studies with individuals with type 2 diabetes will be reviewed in the remainder of this chapter.

2.3.1 Demographic Characteristics

Demographic variables are considered important background influences within social cognition models. In general however, demographic characteristics show little consistent association with self-management behaviours in type 2 diabetes, with the possible exception of age (Glasgow, 1991). This has been positively associated with both diet and glucose testing behaviours (Ruggiero *et al.* 1997) with older age associated with increased behaviour. This contrasts however to exercise behaviour which tends to decrease with greater age (Hays & Clark, 1999; Karter, Ferrara, Darbinian, Ackerson & Selby, 2000; McKean Skaff, Mullan, Fisher & Chesla, 2003).

Exercise has also shown association with gender, with studies showing that females report less exercise than males (Hampson, Glasgow & Foster, 1995; Hays & Clark, 1999). Overall however, the explanatory power of demographic variables in predicting self-care behaviours is typically small (Glasgow *et al.,* 1989; Skelly, Marshall, Haughey, Davis & Dunford, 1995; Glasgow *et al.*, 1997a).

2.3.2 Self-Efficacy

A number of studies have examined self-efficacy as described in Bandura's SCT (Bandura, 1977, 1986). In cross-sectional studies self-efficacy has been found to be a consistent predictor of behaviour (Williams & Bond, 2002; Kavanagh, Gooley & Wilson, 1993; Skelly *et al.,* 1995; Plotnikoff, Brez & Hotz, 2000; Aljasem, Peyrot, Wissow & Rubin, 2001; Senecal, Nouwen, White, 2000; Hays & Clark, 1999; McKean Skaff *et al.,* 2003), with approximately 30% of variance in self-care behaviours explained across a range of studies (Williams & Bond, 2002). In accordance with SCT a greater amount of variance in behaviour is explained when behaviour specific self-efficacy items are used as compared to more general self-efficacy items. This is highlighted by the studies of Kavanagh *et al.,* (1993), Skelly *et al.,* (1995) and William and Bond, (2002) who explained on average 26%-32% of self-care variance with specific items relative to the 4-10% reported by Aljasem *et al.,* (2001) who used more general items. Few prospective studies have considered whether self-efficacy is a predictor of future behaviours, however of those which have Kavanagh *et al.,* (1993) reported that prior self-efficacy is predictive of diet, exercise and blood testing behaviour. Plontikuff *et al.,* (2000) supported these findings in a study looking specifically at exercise behaviour. The results of the study by Plotinkuff *et al.,* (2000) found self-efficacy to be a significant predictor of energy expenditure six months later. Skelly *et al.,* 1995 also reported self-efficacy to be predictive of future exercise and blood glucose testing although not predictive for diet and medication behaviour.

The relationship between self-efficacy and glycaemic control is less clear with some studies suggesting no relationship (Eiser, Riazi, Eiser, Hammersley & Tooke, 2001; Via & Salyer, 1999) whilst others report higher self-efficacy to be associated with better glycaemic control (Day, Bodmer & Dunn, 1996). Similarly the association of self-efficacy and psychological well being is unclear. For example Penninx, van Tilburg, Boeke, Deeg & Kriegsman, (1998) reported a negative association between self-efficacy and depression such that higher self-efficacy was related to lower depression, as did Eiser *et al.,* (2001) when correlation analysis was conducted. In regression analysis however self-efficacy did not predict depression or other aspects of well-being such as anxiety or positive well-being. Similarly Connell, Davis, Gallant & Sharpe, (1994) reported self-efficacy was not a significant predictor of depression.

Two studies measured constructs distinct but with some similarities to self-efficacy, i.e. perceived control (Macrodimitris & Endler, 2001) and sense of mastery, or locus of control (Pouwer *et al.,* 2003). Macrodimitris & Endler, (2001) reported greater perceived control was associated with less depression, anxiety and lower glycosylated hemoglobin levels. Power *et al.,* (2003) reported that the less sense of mastery an individual felt i.e. higher external locus of control, the greater depression reported. The complexity of these findings suggest more prospective research examining the relationship between self-efficacy, or other measures of psychological control, and psychological well-being needs to be conducted.

The relationship of self-efficacy to QoL has been measured infrequently but a positive association, such that higher self-efficacy was related to better QoL was reported in studies by Rose, Fliege, Hildebrandt, Schirop & Klapp, (2002) and McKean Skaff *et al.,* (2003). This relationship only held for European Americans and not Latino Americans in the study by McKean Skaff *et al.,* (2003). This raises an

important issue as to the influence of culture on relationships between psychological constructs and outcomes such as behaviour, QoL or glycaemic control. This study found that amongst European Americans self-efficacy but not a more global construct of control, was associated with self-management behaviours whilst the converse was true for Latino Americans. In addition both self-efficacy and global control were associated with self-reported health amongst European Americans but only global control and not self-efficacy was associated with self-reported health amongst Latino Americans. This study suggests that culture should perhaps be considered more frequently when efforts to understand the relationship between individual differences and health outcomes are made.

2.3.3 *Outcome Expectancies*

Compared to self-efficacy relatively few studies have examined the relationship between OEs and outcomes in type 2 diabetes. For self-management behaviours there is little evidence of association between OEs and dietary behaviours with studies by Skelly *et al.,* (1995), Kingery & Glasgow, (1989) and Williams & Bond, (2002) reporting no relationship. OEs have shown significant positive correlations (Williams & Bond, 2002) and both concurrent and prospective prediction of exercise behaviour in some studies (Kingery & Glasgow, 1989), however in other studies OEs have not been predictive of exercise behaviour (Skelly *et al.,* 1995; Williams and Bond, 2002; Hays & Clark 1999). Similarly although SMBG was predicted by OEs in one study (Skelly *et al.,* 1995) in other studies prediction was not significant (Williams & Bond, 2002; Vincze *et al.*, 2004). SMBG was however predicted by the interaction term of self-efficacy and OEs in the study by Williams & Bond, (2002) such that if OEs and self-efficacy were high then self-care behaviours would also be high, however if confidence in outcomes was high but self-efficacy was low then behaviour would not be promoted.

The relationship between outcome expectancies and glycaemic control has not been reported frequently. The association to psychological well-being has been studied however, for example Eiser *et al.*, (2001) reported that more pessimistic OEs were correlated with higher depression and anxiety but lower positive or general well being. In regression analysis OEs significantly predicted general well-being. In contrast Connell *et al.,* (1994) reported OEs were not significant predictors of depression in a population with depression. The relationship of OEs and outcomes in type 2 diabetes is therefore less clear than for self-efficacy, but appears to have a weaker role in predicting outcomes than does self-efficacy.

2.3.4 *Illness Cognitions*

Although the SRM describes five main attributes of illness representations, (as described in section 2.2.2), studies within diabetes suggest that a slightly different conceptualisation of representations may be helpful (Hampson, Glasgow & Toobert 1990; Hampson, Glasgow & Foster, 1995). The attribute of identity and symptoms is not only important at the time of diagnosis in diabetes but also in the ongoing management of hypoglycaemia and hyperglycaemia. The concept of time-line appears to be less relevant in diabetes than in other illnesses and studies have indicated that 89% of individuals believed that their illness was a chronic condition (Hampson *et al.,* 1990, 1995). In addition questions from the time-line sub-scale correlated highly with those addressing consequences hence it was suggested that a construct labelled seriousness was more appropriate (Hampson *et al.,* 1995). A construct of treatment effectiveness has been highlighted as an important component of illness representations in diabetes, and relates to how likely participants are to believe that different aspects of the diabetes regimen will prevent complications or improve diabetes control, which is similar to the beliefs of cure/control. This slightly different conceptualisation of illness representations in diabetes has been labelled Personal Models of Diabetes (Hampson *et al.,* 1990).

Both cross-sectional and prospective studies have shown personal models of diabetes to be important predictors of self-management behaviours explaining significant variance in diet, exercise and SMBG after demographic and medical variables have been accounted for (Hampson *et al.,* 1995; Glasgow, Hampson, Strycker & Ruggiero, 1997b; Hampson, Glasgow & Stryker, 2000). The strongest predictor of self-management behaviours within personal models was found to be beliefs in treatment effectiveness. There was also some evidence to suggest that regimen specific treatment effectiveness is a stronger predictor than more general measures (Glasgow *et al.,* 1997b).

Personal models of diabetes have also demonstrated association with clinical and psychosocial outcomes (Hampson *et al.,* 1995; Hampson *et al,.* 2000). Specifically a stronger belief in the seriousness of diabetes was related to poorer QoL including physical functioning, mental health components and lower positive affect, but higher negative affect and reported stress. Conversely a stronger belief in treatment effectiveness was associated with better mental health aspects of QoL and positive affect, but lower stress, negative affect and better glycaemic control.

Further support for the influence of illness cognitions on behaviours and clinical and psychosocial outcomes is given in studies that although not specifically based on the SRM, measure constructs which are conceptually similar to personal models of diabetes. For example Wilson, Ary, Biglan, Glasgow, Toobert *et al.,* (1986) found health beliefs, including perceptions of how unpleasant it was to perform management tasks, how effective self-care was for controlling diabetes (similar to treatment effectiveness) and the extent that diabetes interfered with life-style (similar to seriousness), predicted diet, exercise and glucose testing. These beliefs did not however predict taking of medication or glycosylated hemoglobin. Eiser *et al.,* (2001)

also reported that a stronger perception of interference from diabetes (conceptually similar to the construct of seriousness or consequences) was associated with greater depression and anxiety and poorer positive and general well-being. Similarly Connell *et al.,* (1994) reported a positive relationship between perceived threat (again similar to seriousness or consequences) and depression.

It therefore appears that an individual's illness representations are important predictors of behaviour and psychological well-being although the relationship with glycaemic control is less clear.

2.3.5 Readiness to Change

Evidence exploring the association of RTC to outcomes in type 2 diabetes is currently limited, as only a few studies have measured this construct. In one study, which explored RTC dietary behaviours, behaviour improved as individuals moved towards action and maintenance (Vallis, Ruggiero, Greene, Jones, Zinman *et al.*, 2003), however glycaemic control was not improved as RTC increased. Two studies by O'Connor, Asche, Crain, Rush, Whitebird *et al.,* (2004) and Trigwell, Grant & House, (1997) reported that individuals in precontemplation for changing diabetes self-management behaviours have lower HbA1c than those in contemplation, preparation or action, although Trigwell *et al.,* (1997) reported that individuals in maintenance had lower HbA1c than those in contemplation. Trigwell *et al.,* (1997) suggested that this illustrates that HbA1c may influence an individual's motivation to change hence people originally with good control may be less motivated to change and remain in precontemplation. O'Connor *et al.,* 2004 also reported that readiness to change predicted subsequent improvement in HbA1c but only for those with high physical functioning at baseline. It should be noted that this study did not specify that participants had type 2 diabetes.

A linear relationship between RTC and QoL was not apparent when studied by Vallis *et al.,* (2003) as the highest levels of QoL were generally reported at maintenance or pre-contemplation and the lowest levels reported in preparation or contemplation.

2.3.6 Coping

The definition and measurement of coping in studies of individuals with type 2 diabetes varies however results are generally reflective of what would be predicted from the stress coping model (Lazarus & Folkman, 1984). For example diet and exercise behaviours showed positive associations with problem solving skills in a study by Toobert & Glasgow, (1991). Better HbA1c has been associated with an active coping style (Rose *et al.,* 2002) and less denial of the disease (Garay-Sevilla, Malacara, Gutierrez-Roa, 1999). Better adjustment to diabetes has been associated with more problem solving/ supportive coping than evasive, fatalistic or emotive coping (Willoughby, Kee, Demi & Parker, 2000). Similarly instrumental coping has been associated with less depression whilst more avoidance based coping strategies e.g. palliative coping or emotional pre-occupation have been associated with increased anxiety and depression (Macrodimitris & Endler, 2000), however coping was not associated with HbA1c in this last study.

The study by Macrodimitris & Endler, (2000) is of particular interest as perceived control was shown to moderate a number of relationships. For example when perceived control was high the relationship between coping and depression was stable, but if perceived control was low and instrumental coping was low then higher levels of depression were found than if an individual had a low sense of control, but high instrumental coping strategies. Similarly perceived control was reported to moderate the relationship between emotional preoccupation and HbA1c such that for an individual with a low sense of control the relationship between emotional preoccupation and HbA1c was stable, however if the individual had a high sense of

control and low emotional preoccupation then HbA1c was likely to be lower than for an individual with high control and high emotional preoccupation. These interactions highlight the importance of sense of control in outcomes in type 2 diabetes.

2.3.7 Social Support

As reported previously measurement of this construct can either be by structural approaches that assess factors such as size of social network, or more subjective approaches that aim to assess individual's perceptions of social support (McNally & Newman, 1999). Much of the research with patients with type 2 diabetes has used this latter approach. Although not true for all studies (Vincze *et al.,* 2004; Plontikoff *et al.,* 2002) social support has generally shown a positive association with adherence and performance of self-management behaviours in type 2 diabetes (Wilson *et al.,* 1986; Glasgow & Toobert, 1988; Maclean & Lo, 1998; Garay-Sevilla *et al.,* 1995; Tillotson & Smith, 1996; Connell, Fisher, & Houston, 1992; Wang & Fenske 1996; William & Bond 2002). The specificity of support has been found to be important. Glasgow & Toobert (1988), reported that measures of support specific to the different components of the diabetes regimen are stronger predictors of self-care than composite measures of general positive or negative support, and other studies have reported similar findings (Connell *et al.,* 1992, Wilson *et al.*, 1986).

Social support has also been associated with glycaemic control in some (Fukunishi, Horikawa, Yamazaki, Shirasaka, Kanno *et al.,* 1998; Connell *et al.,* 1992) but not all studies (Williams & Bond 2002; Wilson *et al.,* 1986). In the study by Glasgow & Toobert, (1988) although no cross-sectional association was found, social support was found to be a significant predictor of glycaemic control at 6 months follow-up, however this is the converse of findings in the study by Connell *et al.,* (1992) where significant associations but not prediction of HbA1c were reported.

Social support has also shown association with psychological well-being. Receiving instrumental support has been associated with higher depression (Pouwer *et al.,* 2003; Penninx *et al.,* 1998), however, emotional support was not significantly correlated with depression (Penninx *et al.,* 1998). These findings suggest that social support is an important correlate of self-management behaviours and outcomes in type 2 diabetes, but that consideration should be given to type and form of support for efficacy to be expected.

2.4 Implications of Previous Research

From examining the psychosocial literature for individuals with type 2 diabetes it is apparent that constructs from health psychology models can be useful in predicting self-management behaviours and outcomes in type 2 diabetes. The constructs that appeared to show the strongest association to date were, sense of control and in particular self-efficacy, illness representations and social support. This would suggest that these might be particularly important constructs to pay attention to and manipulate when designing self-management interventions for individuals with type 2 diabetes.

CHAPTER THREE: A SYSTEMATIC REVIEW OF SELF-MANAGEMENT INTERVENTIONS IN TYPE 2 DIABETES

3.1 Structure of the Chapter

The current chapter provides an overview of the literature on self-management interventions (SMIs) in type 2 diabetes. The chapter begins with a systematic review of studies that have evaluated the efficacy of SMIs in type 2 diabetes. Tables are provided which describe the studies included in the review. The efficacy of interventions on those outcomes which are evaluated in the current thesis are discussed and where appropriate comparison made to other published reviews of the literature. The extent that studies explore predictors of efficacy following the intervention, and the mechanisms through which change occurs e.g. change in process measures and identification of mediator variables will also be discussed. The review concludes with a summary of the current state of the literature on SMIs in type 2 diabetes and recommendations for future research. Finally the chapter presents the aims of the current thesis and specific hypothesis.

It should be noted that in this thesis two systematic reviews were conducted:

i) A review of SMIs in type 2 diabetes between 1976 and March 2004. A range of outcomes were evaluated in this review and the results, including tables of all studies, are presented in the current chapter.

ii) A review of SMIs in type 2 diabetes between 1976 and 1999. This review was limited to the outcome of glycosylated haemoglobin and results are presented in chapter 4. The aim of this review was to consider the association of intervention components to efficacy, as part of the development phase of the SMI presented in the current thesis. Studies included in this review are included in the table of SMIs presented in chapter three and are all studies up to the end of 1999, this was to avoid

excessive repetition of tables. Within the tables intervention components for studies between 1976 to 1999 are recorded under the heading 'Theoretical Basis (Intervention Components)'.

3.2 Rationale for Systematic Literature Review

In developing a SMI it is useful to consider the theoretical basis of self-management, as was done in chapter two. This can indicate whether particular constructs should be targeted in the intervention. Evaluation of previous interventions however, is also likely to be of benefit as this can indicate whether certain types of intervention and theoretical basis are associated with greater efficacy. The most effective way to evaluate previous interventions is through a systematic review. Systematic reviews aim to combine the results of available evidence in a scientific manner that minimises bias. This is facilitated through explicit description of review methodology and formation of balanced inferences, based on best available evidence (Khan, ter Riet, Glanville, Sowden & Kleijnen, 2001).

SMIs in diabetes have been the topic of several systematic reviews in recent years (Loveman, Cave, Green, Royle, Dunn *et al.*, 2003; Ellis, Speroff, Dittus, Brown, Pichert *et al.*, 2004; Steed, Cooke & Newman, 2003; Corabian & Harstall, 2001; Norris, Lau, Smith, Schmid & Engelgau, 2002a; Norris, Nichols, Caspersen, Glasgow, Engelgau *et al.,* 2002b; Norris, Engelgau, Venkat & Narayan, 2001; Fain, Nettles, Funnell, Charron & Prochownik 1999; Brown, 1988; Brown, 1992; Brown, Upchurch, Anding, Winter & Ramirez, 1996; Brown, 1999; Griffin, Kinmouth, Skinner & Kelly 1998; Padgett, Mumford, Hynes & Carter, 1988). The reviews range from the more focussed for example those concentrating on select patient groups (Norris *et al.*, 2002a, 2001 - type 2 patients), specific study designs (Loveman *et al.*, 2003; Ellis *et al.*, 2004; Corabian *et al.,* 2001- controlled trials) or selected outcomes (Norris *et al.*, 2002a - glycaemic control; Brown *et al.,* 1996 -weight loss; Steed *et al.*, 2003 –

psychosocial outcomes), to those which consider a more mixed set of studies including patients with type 1 or type 2 diabetes, a variety of study designs and a number of outcomes, (Brown, 1988, 1992, 1999; Padgett *et al.,* 1988; Fain *et al.,* 1995). Although there are benefits in including both different study designs and a variety of outcomes in one review it is less desirable to combine studies with both type 1 and type 2 populations in the same review given the different needs of these two populations.

The trend amongst recent reviews has been to examine only randomised controlled trials (RCT) or controlled clinical trials (Loveman *et al.,* 2003; Corabian *et al.,* 2001; Ellis *et al.*, 2004; Norris *et al.,* 2002b, 2001). RCTs are often considered the gold standard for evaluating efficacy in intervention studies, however in diabetes a number of pre-post trials have been conducted and to exclude them from a review potentially excludes valuable data. Glasgow *et al.,* (2003) have also highlighted that study designs other than RCTs are important to consider, particularly when considering the representativeness and uptake of SMIs.

RCTs are also typically included when meta-analyses are conducted. Meta-analysis has however been highlighted as an inappropriate assessment tool when there is considerable variation in the intervention under question, as well as variation in study populations, outcome measurement etc (Newman, Steed & Mulligan, 2004). A more discursive approach is therefore recommended and also facilitates consideration of the association between the theoretical basis or strategies used in an intervention and its efficacy.

Factors such as specificity of study populations, intervention design and method of analysis are important to consider in reviews. To provide a comprehensive understanding of interventions in type 2 diabetes the current review therefore

focuses on the type 2 population, includes both RCT and pre-post trials, and uses a discursive analysis.

3.3. Methods of Systematic Literature Review

3.3.1 Search Strategy

A search of the published literature between 1976 and March 2004 was conducted using the computerised databases Medline, Embase, Psychlit and CINAHL. The search terms used were (Diabetes or Diabetic) plus (Intervention(s) or Trial(s) or Program*) plus (Self-Management or Behav* or Psycho* or Education*) plus (non insulin dependent or maturity onset or type 2). In addition manual searches of the reference lists of retrieved papers and previous reviews were conducted.

3.3.2 Inclusion/Exclusion Criteria

To be included studies had to i) be published in a peer-reviewed English language journal; ii) have a study population of adults (>18 years old) with type 2 diabetes; iii) be either a prospective controlled trial or one-group pretest-posttest design; iv) measured one of the following outcomes - dietary behaviour, exercise behaviour, SMBG behaviour, metabolic control, blood pressure, QoL, psychological well-being (including depression or anxiety) or a psychological process measure e.g. self-efficacy, social support etc; v) evaluated a SMI delivered to patients with type 2 diabetes. A SMI was defined as any intervention that aimed to teach techniques that would help participants improve self-management. Studies were excluded if didactic education was the only component of the intervention as it was recognised that whilst information is necessary it is not sufficient for successful self-management (Coates & Boore, 1996). Interventions that manipulated mode of health care delivery e.g. telephone clinics, outreach visits, were not considered SMIs. In addition, interventions that only taught SMBG, or simply prescribed diet or exercise programmes, were excluded as these are self-management behaviours rather than

interventions to improve such behaviours. (For details on the efficacy of diet, exercise and SMBG manipulation see reviews by Brown *et al.*, 1996; Boule *et al.*, 2001; Coster *et al.*, 2000 respectively). Intensive pharmaceutical or insulin therapy interventions were also excluded as these may have masked any effect of self-management components of the intervention.

3.3.3. Outcomes

The outcomes of interest for the current systematic review were those measured in the current thesis and included i) dietary, exercise & SMBG behaviours (where more than one measure of a behaviour was included results were given for the most positive finding); ii) glycaemic control (HbA1c was used as the primary indicator of glycaemic control where more than one measure was included); iii) blood pressure, iv) QoL; v) psychological well-being, including anxiety and depression; vi) process measures such as self-efficacy, illness beliefs etc. Other outcomes of importance in diabetes e.g. impact on weight loss, were not discussed in the current review but have been reported previously (Brown *et al.*, 1996).

3.4 Results of the Systematic Literature Review

In searching the literature it became apparent that although a majority of the papers identified, restricted the study sample to individuals with type 2 diabetes, there were a number of studies that either did not define type of diabetes, or that used a mixed population of type 1 and type 2 individuals. Typically these latter studies had a majority of type 2 individuals. To avoid excluding these potentially important studies two tables of results are presented. Table 3.1 includes 61 studies where diagnosis with type 2 diabetes was an inclusion criteria. Table 3.2 includes 11 studies where individuals with both type 1 and type 2 diabetes were included in the intervention, but overall the majority of individuals had type 2 diabetes. In both tables, descriptions e.g. follow-up periods, intervention duration are as described in the source paper.

Table 3.1 Summary Table of SMIs in the Type 2 Diabetes Population

Author (specific Group)	N	D	Group Allocation and Intervention Description	Theoretical Basis (Intervention Components)	Findings
Trento et al. 2004/2002/ 2001/1998	112	RCT	**1. Group Education** 4 x 50minute group sessions in years 1& 2 + 7 sessions in years 3-4, in year 5 curriculum started again **2. Individual Education** 8 x 20 minute individual sessions over 2years	Systemic Education Approach GE,GD,ST,B,PS GE	**Follow up at 1year (n=96), 2year (n=103) 4year (n=90), 5year (n=84)** **Behaviour (study developed - redefined as problem solving ability at 5 years)** Significantly better for grp 1 compared to grp 2 at years 1, 2, 4, 5. Grp 1 improved over time while grp 2 deteriorated. SMBG & Smoking – only reported at 2 years no significant differences between grps. **Glycaemic Control (HbA1c)** Significantly better for grp 1 compared to grp 2 at years 2,4,5. No significant differences between grps at year1. Grp 1 remained stable over time while grp 2 deteriorated. **Blood Pressure** Only reported at year 4, no significant differences between grps **Quality of Life (DQOL)** Significantly better for grp 1 compared to grp 2 at years 2, 4, 5, no significant differences at 1 year. Grp 1 improved over time while grp 2 deteriorated. **Knowledge (GISED)** Significantly better for grp 1 compared to grp 2 at years 1,2, 4, 5. Grp 1 improved over time while grp 2 deteriorated.
Toobert et al. 2003 (women only)	280	RCT	**1. Mediterranean Lifestyle Program** 3 consecutive days + weekly 1 hour group sessions for 6 months **2. Usual Care**	Not Stated R,D,Ex	**Follow-up at PI (n=245)** **Behaviour (Exercise flexibility – range of motion)** No significant differences between groups or change from BL **Glycaemic Control (HbA1c)** Significantly better for grp 1 compared to grp 2. Grp 1 improved over time while grp 2 remained stable. **Blood Pressure** No significant differences between groups or change from BL **Quality of Life (SF36 , PAID)** No significant differences between grps on SF36 or

					interpersonal distress scale of PAID. Grp 1 significantly greater improvement on regimen related distress scale of PAID
Pibernik-Okanovic et al. 2004	108	CT	**1. Empowerment Based** 6 weekly 1-1.5 hour group sessions **2. Control**	Patient Empowerment GD,B,PS,SSup	**Follow-up at PI, 3 months, 6 months, n not reported** **Glycaemic Control (HbA1c)** Significant improvement from BL for grp 1 at PI, 3, 6 months. No significant difference from BL for grp 2 at PI, 3, 6 months. No comparison between grps. **Quality of Life (WHOQoL BREF)** Significant improvement from BL for grp 1 at PI on psychological and social domains. No significant differences from BL for physical or environment domains. No significant differences from BL for grp 2. No differences between groups reported. **Predictor Analysis** PI HbA1c predicted by lower HbA1c, better education, greater belief in treatment effectiveness, less perceived consequences of diabetes, greater internal locus of control and weaker belief in chance locus of control at BL. 6month HbA1c predicted by education and belief in treatment effectiveness.
Kirk et al. 2003, 2001	70	RCT	**1. Exercise Intervention** 30 minute individual session + phone calls 1& 3 months after initial session + information leaflet **2. Education Control** 30 minute individual session + phone calls 1& 3 months after initial session + information leaflet	Transtheoretical Model, Motivation & Cognitive Behaviour Therapy GE,B,RP GE	**Follow-Up at 6months (n=63)** **Behaviour (Accelerometer, 7 day recall, fitness)** Exercise - Significant improvement for grp 1 compared to grp 2. **Glycaemic Control (HbA1c)** Significant improvement for grp 1 compared to grp 2. **Blood Pressure** Significant improvement on systolic blood pressure for grp 1 compared to grp 2. No significant differences between grp 1 & 2 for diastolic blood pressure **Quality of Life (SF36, Well-being scale) only reported in pilot study** Significant improvement of grp 1 compared to grp 2 on mental health subscale of SF36. No significant differences between grps on other subscales of SF36 or well-being scale. **Stage of change for exercise behaviour** Significant improvement of grp 1 compared to grp 2.

Goldhaber-Fiebert et al 2003 (Costa Rican)	75	RCT	**1. Nutrition & Exercise Intervention** 11 x 90 minute weekly group session + 3 x 1 hour walking session per week for 12 weeks **2. Usual Care**	Not Stated GE,ST,B, D, Ex GE	**Follow-up at PI (n=61)** **Glycaemic Control(HbA1c)** Significant improvement of grp 1 compared to grp 2 **Blood Pressure** No significant differences between grps 1 & 2
Glasgow et al. 2003, 1999,McKay et al. 2002 Barrera et al. 2002	320	RCT	**1. Internet Based Peer Support** Open access over 10 months **2. Internet Based Self-Management** 2 x 1-2 hour training sessions in use of computer + twice weekly sessions with online coach over 10 months **3. Internet Based Information Only** 2 x 1-2 hour training sessions in use of computer over 10 months	Social Support Theory GE, PS, SSup Self-Efficacy Theory GE, B, PS GE	**Follow-up at PI (n=262)** **Behaviour (Kristal FFB, NCI Block, PASE)** Diet – significant improvement of grp 2 compared to grps 1 & 3 combined. No significant differences between grps 1 & 2 Significant improvement from BL when all grps combined. Exercise – No significant differences between grps. **Glycaemic Control (HbA1c)** Significant improvement of grp 1 compared to grps 2 & 3 combined. No significant differences between grps 1 & 2 **Depression (CES-D)** No significant differences between grps. Significant improvement from BL when all grps combined. **Social Support (DSS)** Significant improvement of grp 1 compared to grps 2 & 3 combined. No significant differences between grps 1 & 2. Significant improvement from BL when all grps combined.
Di Loreto et al. 2003	340	RCT	**1. Exercise Counseling** 1hour individual session, 1 phone call & 15 minute appointment every 3 months **2. Usual Care** 30 minute individual session + appointment every 3 months	Social Cognitive Theory/ Structured Counseling GE,GD,B,PS,D GE	**Follow-Up – 2years (n= 337)** **Behaviour (METS)** Exercise – significant improvement in grp 1 compared to grp 2. **Glycaemic Control (HbA1c)** Significant improvement in grp 1 compared to grp 2. **Process** In grp 1 improvement in HbA1c significantly positively related to increase in energy expenditure.

Tudor-Locke et al. 2002	9	PP	**1. Physical Activity Intervention** 4 weekly group sessions + phone calls for 4 weeks	Social Cognitive Theory GD, B,Ex	**Follow-UP PI, 1month (n=9)** **Behaviour (Pedometers)** Exercise - Improvement compared to BL at PI and 1 month although significance not reported **Blood Pressure** Significant improvement compared to BL at PI and 1 month in systolic BP. No significant change from BL in diastolic blood pressure.
Surwit et al. 2002	108	RCT	**1. Stress Management** 5 weekly group sessions **2. Education Control** 5 wkly 30 minute group sessions	Stress Management GE,B,C,R, GE	**Follow-Up 2,4,6,12months (n=72)** **Behaviour (diet recall, DSAI)** No significant differences between grps at 2,4,6,12 mths **Glycaemic Control (HbA1c)** No significant differences between grps at 2,4, or 6 months. Significant improvement for grp 1 compared to grp 2 at 12 mths. **Anxiety (STAI)** No significant differences between grps at 2,4,6, 12 mths **Quality of Life (GHQ)** No significant differences between grps at 2,4,6, 12 mths **Stress (PSS)** No significant differences between grps at 2,4,6, 12 mths **Predictors** Baseline anxiety did not predict change in HbA1c. Change in diet and exercise not associated with change in HbA1c.
Rickheim et al. 2002	170	RCT	**1. Group Education** 3hour session + 2hour session a fortnight apart + 1hour session at 3,6 months **2. Individual Education** 2x 2hour sessions a fortnight apart + 1hour session at 3,6months	Adult Learning, Health Belief & Transtheoretical Model GE,GD, ST,PS Adult Learning, Health Belief & Transtheoretical Model GE,GD,ST,PS	**Follow-Up 6 months (n=92)** **Behaviour (Exercise Frequency)** Exercise – no significant differences between grp 1 & 2 at 6 months. No significant improvement for either grp from BL. **Glycaemic Control (HbA1c)** No significant differences between grp 1 & 2 at 6 months. Significant improvement for both grps from BL. **Quality of Life (SF36)** No significant differences between grps at 6 months. Significant improvement for both grps from BL on mental sub-scale but not physical sub-scale. **Adjustment (ATT19)** No significant differences between grp 1 & 2 at 6 months. Significant improvement for both grps from BL.

Miller et al. 2002	98	RCT	**1. Nutrition Education** 2hour x 10weekly group session **2. Usual Care Control**	Social Cognitive Theory/ Information Processing/ Learning Theory GE,GD,ST,B	**Follow-Up– PI (n=92)** **Glycaemic Control (HA1c)**-Significant improvement in grp 1 compared to grp 2 at PI.
Keyserling et al. 2002 (African American Women)	200	RCT	**1. Clinic & Community Intervention** Individual monthly visits for 4 months + 2 90 minute group sessions & monthly phone calls then 1group session & monthly phone calls for further 6 months **2. Clinic Intervention** Individual monthly visits for 4 months **3. Minimal Intervention** Information leaflets	Behaviour Change Theory GE, GD, B, SSup,E,D, Behaviour Change Theory GE, GD, B,E,D GE	**Follow-Up 6 (n=179), 12 months (n=171)** **Behaviour (accelerometer, diet recall)** Exercise -No significant differences between grp 1 compared to grp 2 at 6 or 12 months. Significant improvement of grp 1 compared to grp 3 at 12 months but not significant at 6 months. Significant improvement of grp 2 compared to grp 3 at 6 months but not significant at 12 months. Diet - No significant differences between grps at 6 or 12 months **Glycaemic Control (glycosylated haemoglobin)** No significant difference between grps at 6 or 12 months **Quality of Life (MSWB)** No significant difference between grps at 6 or 12 months **Knowledge (DKS)** Significant grp effect on analysis, however unclear where significant differences between grps and over time lie.
Kenardy et al. 2002 (Binge eaters)	34	RCT	**1. Cognitive Behaviour Therapy** 1.5hr x 10 weekly group sessions **2. Non-Prescriptive Therapy** 1.5hr x 10 wkly group sessions	Cognitive Behaviour Therapy GE,C,B,PS Rogerian Principles GE,GD,PS	**Follow-Up PI (n= 29), 3 months (n=29)** **Behaviour (EDI)** Diet - No significant differences between grp 1 & 2 at PI or 3 months. Significant improvement of grps 1& 2 from BL at PI and 3 months. **Mood (WBQ)** No significant differences between grp 1 & 2 at PI or 3 months. Significant improvement of grps 1& 2 from BL at PI and 3 months.

Glasgow et al. 2002, 2000	320	RCT	**1. Combination of all options** 1-2hour individual sessions at 0,3,6months + 7 phone calls + ring binder, newsletters **2. Self-Management + Community Resources.** 1-2hour individual sessions at 0,3,6 months +ring binder, newsletters **3. Self-Management + telephone follow-up** 1-2hour individual sessions at 0,3,6months + 7 calls **4. Self-Management Only** 1-2hour individual sessions at 0,3,6months	Social Learning/Ecologic, Contextual Theories GE,B,PS, Soc Sup GE,B,PS, RP GE,B,PS, Soc Sup, RP Motivational Interviewing, Patient Empowerment GE,B, PS	**<u>Follow-Up 3months (n=293) 6months (n=277), 12months (n= 285)</u>** **Behaviour (Kristal FFB)** Diet – significant improvement of all groups from BL at 3,6,12 months. Grps receiving phone calls significantly better than those without at 3,6 months but not 12 months. **Glycaemic Control (HbA1c)** No significant differences between groups or from BL at 3,6, months. Significant improvement from BL for all grps at 12 months. Grps receiving phone calls significantly better than those without at 12 months. **Quality of Life (Illness Intrusiveness Scale)** Grps receiving community resources less improvement at 3 months but greater improvement at 6 months than those without. Grps receiving phone calls less improvement at 12 months than those without. **Self-Efficacy (Study developed)** No significant differences between groups or from BL at 3,6, months. Significant improvement from BL for all grps at 12 months. Grps receiving phone FU significantly less improvement than those without at 12 months.
Brown et al. 2002, 1999	256	RCT	**1. Community Based Education** 12weekly + 11 biweekly group sessions + sessions at 3,6,12 months (total 52 hours over 1 year) **2. Usual Care Control**	Not Stated GE,GD,ST,PS	**<u>Follow-Up 3,6, 12 months (n- not reported at follow-ups)</u>** **Glycaemic Control (HbA1c)** Significant improvement for grp 1 compared to grp 2 at 6,12 months. No significant differences between grps at 3 months **Health Beliefs (study developed)** No significant differences between grps at 3,6,12 months **Knowledge (study developed)** Significant improvement for grp 1 compared to grp 2 at 3 &12 months.
Anderson-Loftin et al. 2002 (rural African Americans)	23	PP	**1. Culturally Competent Education** 4 x 2hour biweekly group sessions then 5 x 1hour monthly group sessions + weekly phone calls + 1 home visit	Nursing Case Management GE,GD,ST	**<u>Follow-Up 5 months (n=16)</u>** **Behaviour (FHQ)** Diet - Significant improvement from BL. **Glycaemic Control (A1c)** No significant difference from BL.

Sakardi & Rosenqvist, 2001	105	PP	**1. Pharmacy Study Circles** 2 days + 10-12 3hour group monthly sessions	Study Circle Model GE,GD,E	**Follow-Up – 6months (n=105), 12months (n=105)** **Glycaemic Control (HbA1c)** Significant improvement from baseline at 6months. No significant change from baseline at 12 months. **Predictors** Lower BL BMI predicted significantly greater decrease in HbA1c at 12 months follow-up.. Higher BL HbA1c predicted significantly greater decrease in HbA1c at 12 months. Age, education, sex, marital status, diabetes duration, treatment & feelings of loneliness did not predict change in HbA1c at 6 or 12 months
McKay et al. 2001	78	RCT	**1. Internet Based Exercise Programme** Access over 8weeks + 5 individual interactions with coach + access to support area **3. Internet Based Information Only** Access to information over 8weeks	Social Ecological Model GE,B,PS GE	**Follow-Up – PI (n=68)** **Behaviour (BRFSS, Mintues walking per week)** No significant differences between grps at PI **Depression (CESD)** No significant differences between grps at PI **Predictors** Extent of use of programme predicted change in exercise. Individuals who used the programme 3+ times gained more benefits than those who used the programme less.
Cabrera Pivaral et al. 2000	49	RCT	**1. Behaviour Modification** 2hour weekly group sessions for 9 months **2. Education Control** 1.2 hr weekly group sessions for 9 months	Unclear GE,GD,ST GE	**Follow-Up PI (n- not reported)** **Metabolic Control (Serum Glucose)** Significant differences between grps not reported. Significant improvement from BL for grp 1. No significant difference from BL for grp 2.
Ridgeway et al. 1999	56	RCT	**1. Behaviour modification** Individual sessions + 6 monthly 90 minute group sessions for 6 months + 1 session 12months **2. Standard Care Control**	Behaviour Modification GE,B	**Follow-Up 6 (n=38), 12 months (n=38)** **Glycaemic Control (GHb)** No significant differences between groups at 6 or 12 months. Significant improvement for both groups from BL to 6 months but not 12 months **Quality of Life (SF36)** No significant difference between groups at 6, 12 months **Knowledge (Life Skills Test)** Significant improvement of group 1 compared to group 2 at 6 months, not reported at 12 months

Fritsche et al. 1999	64	PP	**1. Structured Teaching** 10 days of inpatient training in groups	Not Stated GE,ST,Ex	**Follow-Up 2years (n=43)** **Behaviour (Freq SMBG)** Significant improvement from BL **Glycaemic Control (HbA1c)** Significant improvement from BL **Blood Pressure** No significant change from BL for systolic or diastolic **Knowledge (Berger et al)** Significant improvement from BL
Vazquez et al. 1998	38	RCT	**1. Nutrition Intervention** 12 weekly +8 bimonthly group sessions **2. Usual Care Control**	Social Learning Theory GD,ST,B,PS,RP	**Follow-Up 3 months (n=36)** **Behaviour (Diet intake)** Significant improvement of grp 1 compared to grp 2 at 3 months
Lustman et al. 1998a,b (depressed)	51	RCT	**1. Cognitive Behaviour Therapy** 1hr biweekly individual sessions + 1hr weekly for 10weeks **2. Education Control** 1 hr biweekly individual sessions over 10 weeks	Cognitive Behaviour Therapy GE,B,PS,C GE	**Follow-Up PI (n= 42), 6months (n=41)** **Glycaemic (GHb)** No significant difference between grp 1 & 2 at PI. Significant improvement of grp 1 compared to grp 2 at 6months. **Depression (BDI)** Significant improvement of grp 1 compared to grp 2 at PI & 6months. **Process** Remission of depression was associated with lower GHb at both PI & 6months **Predictors** BL compliance with SMBG and presence of complications predicted PI depression.
Smith et al. 1997	22	RCT	**1. Behavioural Weight Cont + Motivational Interviewing.** 16 weekly group sessions + 3 individual sessions **2. Beh avioural Weight Control** 16 weekly sessions	Social Cognitive Theory GE,B,PS,D GE,B,D	**Follow-Up PI (n=16)** **Behaviour (Freq SMBG, Exercise)** SMBG - Significant improvement of grp 1 compared to grp 2 at PI. Exercise – Significant improvement of grp 1 compared to grp 2 at PI **Glycaemic (GHb)** Significant improvement of grp 1 compared to grp 2 at PI

Samaras et al. 1997	26	RCT	**1. Exercise Support Group** 6 monthly 1hour group sessions **2. Control**	Precede-Proceed Model GE,B,E	Follow-Up 6months, 12 months (n= not reported at either follow-up) **Behaviour (Food Diary/ METS)** Diet - No significant difference between grp 1 & 2 at 6 or 12months Exercise - No significant difference between grp 1 & 2 at 6 or 12months **Glycaemic Control (GHb)** No significant difference between grp 1 & 2 at 6 or 12months
Jablon et al. 1997	20	RCT	**1. Relaxation Training** 8, 1hour individual sessions over 4 weeks + practice with audiotapes **2. Usual Care Control**	Stress Management R,BIO	Follow-Up PI (n=19) **Glycaemic Control (Fructosamine)** No significant differences between grps 1 & 2 at PI **Anxiety (STAI)** No significant differences between grps 1 & 2 at PI. Significant improvement from BL for grp 1 when grp 2 had also undergone treatment. **Predictors** BL anxiety and blood glucose did not predict PI blood glucose
Henry et al. 1997	21	RCT	**1. Cognitive Behavioural Stress Management** 6 weekly 1.5 hour group sessions **2. Usual Care Control**	Cognitive Behaviour Theory B,PS,C,R	Follow-Up –PI (n= 19) **Glycaemic Control (HbA1c)** Significant improvement for grp 1 compared to grp 2 at PI **Depression (BDI)** Significant improvement for grp 1 compared to grp 2 at PI **Anxiety (STAI)** Significant improvement for grp 1 compared to grp 2 at PI **Stress (Hassles Scale – Kanner et al.)** Significant improvement for grp 1 compared to grp 2 at PI **Coping Ability (Kanner et al.)** No significant differences between grps at PI **Process** Change in HbA1c not associated with change in anxiety, depression, stress or coping. Change in anxiety associated with change in coping, change in stress associated with change in depression.
Aikens et al. 1997	22	RCT	**1. Relaxation Training** 6, 1hour group sessions over 8weeks	Stress Management GE,GD,R	**Follow-Up – PI (n=22), 2months (n=22)** **Glycaemic Control (GHb)** No significant differences between grp 1 and 2 at PI or

			2. Usual Care Control		2months **Anxiety (GSI)** No significant differences between grp 1 and 2 at PI or 2months **Predictor** BL anxiety not associated with change in HbA1c
Agurs-Collins et al. 1997 (African Americans)	64	RCT	**1. Weight Loss & Exercise Program** 12 weekly 90 min group session + 1 individual session + 6 biweekly session in 3months **2. Minimal Intervention** 1 session in first 3 weeks + 2 information mailings	Social Action Theory GE,GD,PS,B,RP,D,E GE	**<u>Follow-Up 3 months (n=58), 6 months (n=55)</u>** **Behaviour (Food Frequency Questionnaire, PASE)** Diet – significant improvement of grp 1 compared to grp 2 at 3 months. No significant differences between grps at 6months Exercise - significant improvement of grp 1 compared to grp 2 at 3 months. No significant differences between grps at 6months **Glycaemic Control (HbA1c)** Significant improvement of grp 1 compared to grp 2 at 3 & 6 months **Blood Pressure** No significant differences between grp 1 & 2 for systolic blood pressure at 3 & 6 months or diastolic blood pressure at 3 months. Significant improvement of grp 1 compared to grp 2 at 6months for diastolic blood pressure. **Knowledge (Nutrition knowledge)** Significant improvement of grp 1 compared to grp 2 at 3 months. No significant differences between grps at 6months **Process** Increase in carbohydrate intake was associated with decrease in HbA1c at 3 months **Predictors** Physical activity, weight, dietary or demographic variables & knowledge did not predict change in HbA1c at 3 or 6months. Baseline HbA1c predicted change in HbA1c at 3 & 6month
Gruesser et al. 1996	240	PP	**1. Structured Teaching** 5 x 2hour group sessions over 4weeks	None Stated GE,GD,ST	**<u>Follow-up – median 6months (n=160)</u>** **Glycaemic Control (HbA1)** Significant improvement from baseline

Garcia & Suarez 1996	186	PP	**1. Interactive Education** 1.5hour monthly group sessions for 5 years	None Stated GD,PS,SSup	**Follow-up 5 years (n= 148)** **Behavioural Skills (Observation)** Significant improvement from baseline **Adherence (Dr's opinion, patient feedback)** Significant improvement from baseline **Glycaemic Control (HbA1c)** Significant improvement from baseline **Knowledge (Garcia et al.)** Significant improvement from baseline
Campbell et al. 1996	238	RCT	**1. Behavioural Program** 3 individual sessions in 4weeks + a minimum of 3 more sessions but as needed **2. Group Education** 2x 1hour individual session + 3 day group session + 2hour lecture + group sessions at 3, 9 months **3. Individual Education** 2 x1hour in 2 weeks + 12, 30 minute monthly individual sessions + 2hour lecture **4. Minimal Intervention** 2 x 1hour in 2 weeks	Cognitive Behaviour Therapy GE,B,C,PS,SSup None Stated GE, ST None Stated GE None Stated GE	**Follow-up 3 months (n=180), 6 months (n=98), 12 months (n=64)** (N.B Attrition varied by group and outcome) **Glycaemic Control (HbA1)** No significant differences between groups at 3,6,12 months **Blood Pressure** No significant differences between groups at 3,6,12 months for systolic at 3,6,12 months. No significant differences between groups at 3,6,months for diastolic. Significant improvement for grp 1 compared to grp 2 & 3 for diastolic at 12months **Knowledge (DKNA)** Significant improvement for grp 1 compared to grp ,3 & 4 at 3, 6 months. Significant improvement for grp 2 compared to grp 3 at 6mth & grp 4 at 3 & 6months. No significant differences between grps at 12months.
Pieber et al. 1995	107	CT	**1. Structured Teaching** 4 weekly 2hour group sessions **2. Usual Care Control**	None Stated GE,GD,ST	**Follow-Up 6months (n=94)** **Glycaemic Control (HbA1c)** Significant improvement of grp 1 compared to grp 2 at 6months **Blood Pressure** No significant differences between grps at 6months for systolic. Significant improvement of grp 1 compared to grp 2 at 6months for diastolic. **Knowledge (measure used by Kronsbein 1988)** Significant improvement of grp 1 compared to grp 2 at 6months
Pascale et al.1995	44	PP	**1. Behavioural Weight Loss** 16 weekly group sessions + group sessions at 1,2,4 6months post intervention	Behaviour Modification GE,GD,B,PS,D	**Follow-Up – PI (n=31), 1 year (n=31)** **Glycaemic Control (HbA1c)** Significant improvement compared to BL

Guare et al. 1995	20	PP	**1. Behavioral Weight Loss** 16 weekly group sessions	Behaviour Modification GE,B,D,E	**Follow-Up PI (n=19)** **Behaviour (3 day food record, Paffenberger activity qnaire)** Diet – significant improvement from BL Exercise - significant improvement from BL **Depression BDI** Significant improvement from BL
Domenech et al. 1995	124	CT	**1. Structured Teaching** 4 weekly 2hour group sessions **2. Usual Care Control**	None Stated GE,GD,ST,D	**Follow-Up 1year (n=79)** **Glyceamic Control** No significant differences between grps at 1 year **Knowledge (20 item questionnaire)** Significant improvement for grp 1 from BL. Not measured in grp 2
Basa & McLeod 1995	49	PP	**1. SM** (Education Program) 12 hours over 2 days	None Stated GE,ST	**Follow-Up PI, 3months, 6months (n=39)** **Glycaemic Control (HbA1c)** Significant improvement from baseline at PI, 3, 6 months **Quality of Life (Tupling et al.)** Significant improvement from baseline at PI 3 months, not measured at 6 months. **Adjustment (ATT39)** Significant improvement from baseline at PI 3 months, not measured at 6 months **Knowledge (MDRTK)** Significant improvement from baseline at PI, 3, 6 months
Wierenga, 1994	66	RCT	**1. Weight Control Prog** 5 x 1.5hour weekly group sessions **2. Control**	Behaviour Modification B, SSup	**Follow-Up PI(n=48), 4months (n=48)** **Behaviour (HPS)** Significant improvement of grp 1 compared to grp 2 at PI but not 4 months **Quality of Lif e(DHS)** No significant differences between grps at PI or 4months **Social Support (PRQ)** No significant differences between grps at PI or 4months **Correlation analysis** between factors Knowledge assoc. HPS, PRQ assoc HPS, DHS, HPS assoc DHS. Knowledge and social support , health practices predict health status

Muchmore et al. 1994	23	RCT	**1. SMBG & Carbohydrate Counting** Individual sessions at week 1,3, 24 + 4 weekly group sessions then 4 monthly group sessions **2.Education Control** Individual sessions at week 1,3, 244 weekly group sessions then 4 monthly group sessions	None Stated GE,ST GE,GD	**Follow-Up 44 weeks (n=23)** **Glycaemic Control (HbA1c)** No significant differences between grps at 44 weeks **Quality of Life (DQOL)** No significant difference between groups on any scale at 44 weeks. **Predictor analysis** No relationship between change in HbA1c and duration of diabetes, initial HbA1c or frequency of SMBG
Robison 1993	12	RCT	**1. Group Counselling** 12 x 1hour weekly group sessions **2. Usual Care Control**	Unclear GE,GD,B,PS,	**Follow-up 12, 24, 36, 48weeks (n – not reported)** **Behaviour (Dietary deviations)** Significant improvement of grp 1 compared to grp 2 at 24 & 48 weeks but no significant differences between grps at 12 or 36 weeks **Glycaemic Control (Mean wkly peak blood glucose level)** Significant improvement of grp 1 compared to grp 2 at 24 weeks but no significant differences between grps at 12,36 or 48weeks
Lane et al. 1993 (in poor control)	38	RCT	**1. Intensive Education & Clinical Management + Relaxation Training** 8 weekly 50 minute + individual sessions + individual sessions at 3,4,5,8,10month **2. Intensive Education & Clinical Management** 8 weekly individual sessions + individual sessions at 3,4,5,8,10mth	Stress Management GE,R,Bio GE	**Follow-Up 8,16,24,32,40,48weeks (n=32)** **Glycaemic Control (HbA1c)** No significant differences between grps at any follow-up **Predictor analysis** No significant association between anxiety, locus of control, extraversion, neuroticism and change in GHb
Laitinen et al.1994 obese	86	RCT	**1. Intensified Dietary Therapy** 6 clinic visits in 12 months **2. Control**	None Stated GE, B,ST	**Follow-Up – 15 months (n= not stated)** **Behaviour (Food records, Exercise questionnaire)** No significant differences between grps at 15months **Glycaemic Control (HbA1c)** Significant improvement of grp 1 compared to grp 2 at 15months **Predictors** Higher HbA1c at BL associated with decreased HbA1c at 15months

Gruesser et al. 1993	80	PP	**1. Structured Teaching** 4 x 2hour weekly group sessions	None Stated GE,GD,M,ST	**Follow-up - 5months n= 174 beh, 80 HbA1c)** **Behaviour (Freq urine testing)** Significant improvement compared to BL **Glyceamic Control (HbA1c)** Significant improvement compared to BL
Boehm 1993	156	RCT	**1. Behavioural Instruction** 1hour group session + varied by individual **2. Behavioural Strategies** Varied by individual **3. Compliance** Varied by individual **4. Attention Control** Varied by individual	Social Cognitive Theory GE,B B B	**Follow-Up PI– (n- not stated)** **Glycaemic Control (HbA1c)** No significant differences between grps **Predictor Analysis** Increased age, unemployment associated with greater decreases in GHb for all grps. No association of gender.
Blonk et al. 1993	60	RCT	**1. Weight Control Programme** 8 weekly group sessions then sessions at 4,8,12,16,20 months + exercise sessions 2xs/week for months 3-6 and 1/week for month 9-12 and 15-18 **2. Control**	Behaviour Modification GE, B,C, RP,D,Ex GE,D	**Follow-up 6,12months, 2year (n=53)** **Glycaemic Control (HbA1c)** Significant improvement of grp 1 compared to grp 2 at 6months but not 12months or 2 years **Blood Pressure** No significant differences between grps at 6 or 12 months or 24mths
Welch & Smith, 1992	27	PP	**1. Weight Control Programme** 11 group sessions	Cognitive Behaviour Theory GE,GD,B,C,R D,Ex	**Follow-up PI (n=21)** **Glycaemic Control (HbA1c)** Significant improvement from BL at PI
Marcus et al. 1992, Wing et al. 1991a	66	PP	**1. Behavioral Weight Loss** 20 weekly group sessions + 4 booster sessions over 52 weeks	Behaviour Modification GE, B,C,RP, D,E	**Follow-up PI (n= not reported)** **Glycaemic Control (HbA1c)** Significant improvement from BL **Depression (BDI)** Significant improvement from BL
Glasgow et al. 1992	102	RCT	**1. Self-Management** 8weekly + 2fortnightly + 16 exercise group sessions **2. Control group**	Social Cognitive Theory GE,GD,B,PS,RP,E	**Follow-up PI (n=101), 6 mth (n=48)** **Behaviour (Block, food record, Stanford 7 day recall, minutes activity per day)** Diet – significant improvement for grp 1 compared to grp 2 at PI. Exercise – significant improvement grp 1 compared to grp 2 at PI SMBG - significant improvement for grp 1 compared to grp 2 at PI **Glycaemic Control (HbA1c)** No significant differences between grps at PI

					Quality of Life (DQOL) no significant differences between grps at PI **Self-Efficacy (developed by authors)** No significant differences between grps at PI **Mood (GDS, PESOP)** No significant differences between grps at PI **Problem Solving (developed by authors)** significant improvement for grp 1 compared to grp 2 at PI. **Process** No association between change in exercise or diet and change in HbA1c
D'Eramo Melkus et al. 1992	82	RCT	**1. Group Education + Individual Session** 11 x 2hour weekly group session + 3 individual sessions **2. Group Education** 11 x 2hour weekly group sessions + 1 individual session **3. Usual Care Control**	Not Stated GE,GD,PS GE,GD GE	**<u>Follow-Up 3 months (n=61), 6months (n=49)</u>** **Glycaemic Control (HbA1c)** Significant improvement of grp 1 &2 compared to grp 3 at 3 & 6 months **Knowledge (not referenced)** No significant difference between grps at 3 or 6 months **Locus of Control (MHLC)** No significant difference between grps at 3 or 6 months
Calle-Pascual et al. 1992	74	CT	**1. Behaviour Program** 1 individual session + 3 x 3hour group session in 1 week + 4 sessions in 1year **2. Usual Care Control** 2 sessions in clinic	Behaviour Modification GE,B,ST GE	**<u>Follow-Up PI (n=74, but unclear if any attrition)</u>** **Glycaemic Control (Fasting serum glucose)** Significant improvement of grp 1 from BL. No significant change from BL for grp 2. No comparison between grps. **Blood Pressure** Significant improvement of grp 1 from BL in systolic & diastolic. No significant change from BL for grp 2 in systolic & diastolic. No comparison between grps.
Wing et al. 1991b	49	RCT	**1. Family Based Behavioural Weight Loss** 12 weekly 1hour group session + 4 biweekly group sessions + 4 group sessions at weeks 24, 28, 40 & 72 **2. Independent Behavioural Weight Loss** 12 weekly 1hour group sessions + 4 biweekly group sessions + 4 group sessions at weeks 24, 28, 40 & 72	Behaviour + Social Support B,PS,C,SSup, D B,PS,C,D	**<u>Follow-up PI, 1year (n=43)</u>** **Behaviour (Food diary, EBI, Paffenbarger)** Diet - significant improvement grp 2 compared to grp 1 in decrease in calories at PI. No significant differences between grps on other dietary measures at PI or 1 year Significant improvement from BL for both grps at PI & 1year Exercise – no significant differences between grps at PI or 1year. Significant improvement from BL for both grps at PI & 1year

					Glycaemic Control (HbA1c) No significant differences between grps at PI or 1 year. Significant improvement from BL for both grps at PI but not significant at 1 year.
Campbell et al. 1990	70	RCT	**1. Intensive Education** 35.5 hrs over 11weeks **2. Education Control** 14 hours over 3 days	Cognitive Motivation Theory GE,ST,B,PS,C GE	**<u>Follow-up 1month, 3 months, 6months (n=62)</u>** **Behaviour (Food records)** Significant improvement of grp 1 compared to grp 2 on 5 out of 10 dietary assessments across follow-ups **Glycaemic Control (Fructosamine)** No significant differences between grps across follow-ups
Wing et al. 1988	20	RCT	**1. Behavioural Weight Control + Self Regulation** 10 weekly group sessions + 3 biweekly group sessions + 6 biweekly group sessions + 3montly sessions **2. Behavioural Weight Control + Monitoring** 10 weekly group sessions + 3 biweekly group sessions + 6 biweekly group sessions+ 3 monthly sessions	Self-Regulation Model GE, ST,B,PS,C,D,E GE,ST,B,PS,C,D,E	**<u>Follow-Up PI (n=20), 1year (n=17)</u>** **Behaviour (Daily Diaries)** Diet. No significant differences between grps at PI, change from BL not reported. Exercise. No significant differences between grps at PI, change from BL not reported. **Glycaemic Control (HbA1c)** No significant differences between grps at PI or 1year, change from BL not reported.
Kronsbein et al. 1988	127	RCT	**1. Structured Teaching** 4 x 2hour weekly group sessions **2. Control**	None stated GE,GD,ST	**<u>Follow-Up 1year (n=99)</u>** **Behaviour (diaries)** SMBG. Significant improvement of grp 1 compared to grp 2 at 1 year **Glycaemic Control (HbA1c)** No significant differences between grps at 1 year **Knowledge (study developed)** Significant improvement of grp 1 compared to grp 2 at 1 year

Pratt et al. 1987	79	CT	**1. Peer Support** 8 x 2 hour weekly group sessions + 2 x 2hour monthly group sessions **2. Education** 8 x 2 hour weekly group + 2 x 2hour monthly group **3. Control**	None Stated GE,GD,ST,B,PS,C GE,GD,ST	**Follow-Up weeks 8, 16 (n= not stated)** **Glycaemic Control (glycosylated hemoglobin)** No significant differences between grps at weeks 8 or 16. **Social Support (Arizona Social Support Scale)** Significant improvement of grp 1 compared to grp 2 at week 8 **Predictor Analysis** Adaptation to diabetes and peer support but not personal or medical support positively significantly associated with change in GHb at week 8 and week 16. No association between beliefs about susceptibility to rises in glucose or complications or frequency food or emotions threatened compliance to change in GHb at week 8 or 16. Frequency of social problems threatening compliance significantly negatively associated with change in Ghb at week 16 but not week 8
Heitzman et al. 1987	55	RCT	**1. Cognitive-Behaviour Modification** 7, 1.5hour weekly group sessions **2.Cognitive Modification** 7, 1.5hour weekly group sessions **3. Behaviour Modification** 7, 1.5hour weekly group sessions **4. Relaxation Control** 7, 1.5hour weekly group sessions	Cognitive Behaviour Theory B,C Cognitive Theory C Behavioural Theory B Stress Management GE,R	**Follow-Up 2,6,13,18months (n=46)** **Glycaemic Control (HbA1c)** No significant differences between grps at any follow-up.

Kaplan et al. 1987 Hartwell et al. 1986	76	RCT	**1. Behavioural Diet & Exercise Intervention** 10, 2hour weekly group sessions **2. Behavioural Diet Int.** 10, 2hour weekly group sessions **3. Behavioural Exercise Int.** 10, 2hour weekly group sessions **4. Education Control** 10, 2hour weekly group sessions	Cognitive Behaviour Modification/Learning Theory GD,B,C,R,D,Ex GD,B,C,R.D GD,B,Ex GE	**Follow-Up 18months (n-=70)** **Glycaemic Control (HbA1c)** Significant improvement of grp 1 compared to grp 4 at 18months. No significant differences between grps 2,3,4 at 18months. **Quality of Life (Kaplan et al. 1984)** Significant improvement of grp 1 & 2 compared to grp 4. No significant differences between grp 3 & grp 4 at 18months **Correlation analysis** Improvement in quality of life associated with decrease in HbA1c
Falkenberg et al. 1986	46	RCT	**1. Problem Orientation** 8 2hour group sessions over 3 months **2. Control** 1 day	Learner Activity GE, GD GE	**Follow-Up PI, 6months (n=33)** **Behaviour (Food questionnaire, questioning)** Diet – no significant differences between grp 1 & 2 at PI **Glycaemic Control (Hb-A1)** Significant improvement of grp 1 compared to grp 2 at PI but no significant differences between grps at 6months **Knowledge (study developed)** Significant improvement of grp 1 compared to grp 2 at 6months
Wing et al. 1986	50	RCT	**1. Behavioral Weight Control + Self-Monitoring** 12 weekly group session + 6 monthly group session + sessions at 9 & 12months **2. Behavioral Weight Control** 12 weekly group sessions + 6 monthly group sessions + sessions at 9 & 12months	Behaviour Modification GE,GD,B,ST, SSup, D GE,GD,B,SSup, D	**Follow-Up week 12, week 62 (n=50)** **Behaviour (Self-report diaries)** Diet - Significant improvement of grp 2 compared to grp 1 for calorie intake at week 12. No significant difference between grps on sugar or fiber consumption at week12 or 62, change from BL not reported. Exercise - No significant difference between grps on sugar or fiber consumption at week12 or 62, change from BL not reported. **Glycaemic Control (GHb)** No significant differences between grp 1 & 2 at week 12 or 62. But both grps significantly improved between BL and week 12 **Blood Pressure** No significant differences between grp 1 & 2 at week 12 or 62 for diastolic or systolic. No change from BL for DBP. Significant improvement form BL for SBP **Depression (BDI)** No significant differences between grps at week 12 or 62. Grps significantly improved between BL and week 12

White et al. 1986	41	RCT	**1. Group Management** 4 weekly group + 2 biweekly group +4 monthly group sessions **2. Education Control** 4 weekly group + 2 biweekly group +4 monthly group sessions + 1 individual session	Group Decision Process GD,PS GE	<u>Follow-Up: PI (n=32)</u> **Glycaemic Control (Glycohemoglobin)** No significant differences between grps 1 & 2at PI **Knowledge (20 item no reference)** No significant differences between grps at PI, but both improved at PI compared to BL **Correlation Analysis** At BL no association betweeh glycohemoglobin, age, duration of disease, age at onset, insulin dose, marital status, education, or knowledge. Greater internal locus of control was significantly associated with lower glycohemoglobin. **Predictor Analysis** No significant association between BL internal locus of control and change in glycohemoglobin
Surwit & Feinglos, 1983	12	CT	**1. Relaxation** 5 x 50minute individual sessions over 5 days **2. Control**	Stress Management R,Bio	<u>Follow-Up PI (n=12)</u> **Glycaemic Control (plasma glucose)** Significant improvement of grp 1 compared to grp 2 at PI.

N= number of participants who were enrolled and fitted inclusion criteria at baseline, **BL**- baseline, **PI** – Post-intervention, **Grp** – Group, **D- Design** (RCT – Randomised Controlled Trial, CT – Controlled Trial, PP – Pre-Post Trial), **Intervention Components** (B- Behaviour Therapy , Bio – Biofeedback, C- Cognitive Therapy, D- Diet, E – Exercise, GD – general discussion, GE – general education, Mis – Miscellaneous, PS-Problem Solving, R – Relaxation, RP – Relapse Prevention, Ssup – Social Support , ST- skills training) **Measures** (BDI – Beck Depression Inventory, BRFSS – Behavioural Risk Factor Surveillance System, CES-D – Center for Epidemiologic Studies – Depression scale, DASI – Duke Activity Status Index, DKS – Diabetes Knowledge Scale, DAS – Diabetes Attitude Scale, DCP- Diabetes Care Profile, DQOL – diabetes quality of life questionnaire, DSS – Diabetes Support Scale, DHS – Diabetes Health Status ,EDE – Eating Disorders examination, EDI – Eating Disorders Inventory, FHQ – Food Habits Questionnaire, GISED – Gruppo di Studio per l'Educaziione sul Diabetes , GSI - General Severity Index, GHQ – General Health Questionnaire, GDS – Geriatric Depression Scale, HPS – Health Practices Survey , Kristal FFB – Kristal Fat and Fiber Behaviour Scale, Kristal FHQ – Kristal Food Habits Questionnaire, METS – evaluation of energy expenditure, M& SWB – Mental and Social Well Being, MDRTKQ – Michigan Diabetes Research and Training Knowledge Questionnaire, MHLC – multidimensional health locus of control, NCI Block – Block/NCI Fat screener, PAID – Problem Areas in Diabetes, PASE – Physical Activity Scale for the Elderly, PSS – Perceived Stress Scale, PRQ – Personal Resources questionnaire, PESOP – Pleasant Events Scale Older People, QSD – Questionnaire on Stress in Diabetes, SF-36 Short Form 36, STAI – Spielberger State-Trait Anxiety Inventory, ,WBQ – Well Being Questionnaire, WHOQoL BREF – world health organisation quality of life questionnaire, brief)

Table 3.2 Summary Table of SMIs in Studies with a Mixed Type 1 and Type 2 Population.

Author (specific group)	N	D	Group Allocation and Intervention Description	Theoretical Basis (Intervention Components)	Findings
Keers et al. 2004	58	PP	**1. Patient Empowerment – Multidisciplinary Intensive Education Programme** 2 days a week for 5 weeks, individual and group sessions + 2 visits after 6 and 12 weeks	Patient Empowerment GE,GD,B,C	**Follow-up PI, 3months (n=51)** **Glycaemic Control (HbA1c)** Significant improvement from BL at 3months. **Quality of Life (SF36)** Significant improvement from BL at 3months on health change scale, but no significant change on other sub-scales. **Health Locus of Control (MHLC)** Significant change from BL in belief in internal control (increase) and belief in powerful others (decrease) at PI. **Knowledge (DKS)** Significant improvement from baseline. **Predictor analysis** BL HbA1c significantly predicts change in HbA1c at PI (poorer BL HbA1c associated with greater change), no other variables are predictors. Change in physical functioning predicted by Age, physical functioning at BL (lower BL, greater change) and change in belief in chance locus of control (larger reduction in belief of chance greater increase in physical functioning). Change in social and mental functioning predicted by BL social and mental functioning respectively (lower BL greater change). No predictors of change in general health perception identified. Change in health change predicted by BL health change and change in internal locus of control (increase in internal control greater increase in health change).

Jones et al. 2003	102	RCT	**1. Pathway to Change** Monthly mail or phone contacts for 6 months + handbook. (50% also received free SMBG strips) **2. Usual Care** (50% received free SMBG strips)	Transtheoretical Model GE,B	**<u>Follow-up at PI (n = unclear)</u>** **Behaviour (SMBG frequency, NCI Block, quit smoking).** SMBG - Significant improvement for grp 1 compared to grp 2. Diet–Significant improvement for grp 1 compared to 2. Smoking - Significant improvement for grp 1 compared to grp 2 grp. **Glycaemic Control (HbA1c)** Results unclear. **Stages of Change (study developed)** Significant improvement for grp 1 compared to 2 for SMBG, dietary and smoking behaviour).
Peyrot et al. 1999,1997 *1993, 1991, 1989	634	PP	**1. Coping Skills Training** 37 hours of individual and group sessions over 5 days	Cognitive-Behavioural Psycho-Educational GE,GD,ST,B,PS,C,RP	**<u>Follow-Up PI (n=578), 6months (n=246), 12months (n=155)</u>** **Depression (CESD)** Significant improvement from BL at PI and 6months. **Anxiety (ZSRA)** Significant improvement from BL at PI and 6months. **<u>Follow-Up 6mth (n=124), 12mth (n=91)</u>** **Glycaemic Control (HbA1c)** Significant improvement from BL at 6,12months. **Behaviour (self-reported in previous month)** SMBG Significant improvement from BL at 6,12months. Diet Significant improvement from BL at 6 months no significant change from BL at 12months on binge eating. Exercise Significant improvement from BL at 6 months no significant change from BL at 12months. **Self-Esteem (Rosenberg measure)** Significant improvement from BL at 6,12months. **Self-Efficacy (Grossman measure)** Significant improvement from BL at 6,12months. **Knowledge(DKN)** Significant improvement from BL at 6,12months.

Glasgow et al. 1997c, 1996, 1995	206	RCT	**1. Office Based Intervention** 2x 20minute individual sessions + 30minute video + 2 phone calls **2. Control**	Social Cognitive Theory GE,B,PS	**Follow-Up 3months (n=180) 12months (n=173)** **Behaviour (Kristal FHQ, 4 day food records)** Significant improvement of grp 1 compared to grp 2 at 3 & 12months. **Glycaemic Control (HbA1c)** No significant differences between grps at 3& 12months. **Quality of Life (SF36)** No significant differences between grps at 3 months, not reported at 12months. **Patient Satisfaction with Clinic Visit(study dev)** Significant improvement of grp 1 compared to grp 2 at 3 & 12months. **Predictor Analysis** No significant predictors of improvement in HbA1c identified. Primarily belief about diabetes and barriers to dietary adherence significant predictors of diet behaviour.
Anderson et al. 1995	64	RCT	**1. Patient Empowerment** 6 weekly 2hour group sessions **2. Control Group**	Social Cognitive Theory /Empowerment GE,GD,B,PS,Ssup	**Follow-Up PI (n= 45)** **Glycaemic Control (glycated hemoglobin)** Significant improvement of group 1 compared to group 2 at PI. **Self-Efficacy (study developed)** Significant improvement of group 1 compared to group 2 on 4 out of 8 sub-scales at PI. **Attitudes (DAS, DCP)** Significant improvement of group 1 compared to group 2 on 2 out of 5 sub-scales.
Zettler et al. 1995	17	PP	**1. Coping with Fear Complications.** 6 x 1.5 hour group sessions + 1 x 3hour group session	Behaviour Modification GD,B,C,SSup,R	**Follow-Up PI, 3 months (n= not stated)** **Glycaemic Control (HbA1)** No significant differences between grps at PI or 3months. **Stress (QSD)** Significant improvement compared to BL on 3 of 10 sub-scales at PI & 3months.
Wooldridge et al. 1992	189	PP	**1. Education Programme** ≈ 8 individual sessions over 2-3 months	Health Belief Model & Locus of Control GE,C	**Follow-Up PI (n=104)** **Glycaemic Control (HbA1c)** Significant improvement from BL for type 2 individuals at PI. **Beliefs (study developed)** Significant improvement from BL on 4 out of 6 sub-scales.

					Correlation Analysis Higher belief in internal locus of control associated with PI perceived benefits of treatment and perceived ability. Higher belief in powerful others associated with less perceived severity. Higher belief in chance locus of control associated with less belief in perceived severity and barriers to treatment.
Maxwell et al. 1992	204	RCT	**1. Education and Support Group** 3 days in groups + 8 x 75minute group sessions **2. Education Control** 3 days in groups	Support Group GE,GD GE	**<u>Follow-Up – 7months (n=134)</u>** **Behaviour (self-reported frequencies)** No significant differences between grps at 7 months. **Glycaemic Control (glycated hemoglobin)** No significant differences between grps at 7 months. **Knowledge (DKN)** No significant differences between grps at 7 months. **Adjustment (ATT39)** No significant differences between grps at 7 months. **Locus of Control (Wallston)** No significant differences between grps at 7 months.
Gilden et al. 1992	32	PP	**1. Education + Support** 6 weekly sessions + 18monthly group sessions **2. Education** 6 weekly group sessions **3. Control**	None Stated GE,GD,ST, Mis GE,ST,Mis	**Follow-up 2years (n= not reported)** **Glycaemic Control (HbA1c)** Significant improvement of grp 1 & 2 compared to grp 3 No significant differences between grp 1 & 2. **Depression (Zung)** Significant improvement of grp 1 compared to grp 2 & 3 at 2years. **Knowledge (Study developed)** Significant improvement of grp 1 compared to grp 2 & 3 at 2years. **Quality of Life (not referenced)** Significant improvement of grp 1 compared to grp 2 & 3 at 2years. **Stress (adapted from ATT39** Significant improvement of grp 1 compared to grp 3 at 2years.

Bernbaum et al. 1989	29	PP	**1. Self-Management for Visually Impaired** 3 weekly sessions x 12	GE,GD,ST,E	**Follow-Up PI** **Depression** Significant improvement from BL at PI
Mazzuca et al. 1986	532	RCT	**1. Systematic Education** Varied by individual - mean 2.5, x1.5hour sessions **2. Control**	GE,ST,B GE	**Follow-Up PI (n=275)** **Behaviour (calorie intake, medication compliance)** Diet – significant improvement of grp 1 compared to grp 2 at PI. Medication – no significant differences between grps at PI. **Glycaemic Control (HbA1)** significant improvement of grp 1 compared to grp 2 at PI. **Blood Pressure** significant improvement of grp 1 compared to grp 2 at PI on both systolic and diastolic. **Knowledge (study developed)** Significant improvement of grp 1 compared to grp 2 on 2 out of 9 areas at PI.

N= number of participants who were enrolled and fitted inclusion criteria at baseline, **BL**- baseline, **PI** – Post-intervention, **Grp** – Group, **D- Design** (RCT – Randomised Controlled Trial, CT – Controlled Trial, PP – Pre-Post Trial), **Intervention Components** (B- Behaviour Therapy , Bio – Biofeedback, C- Cognitive Therapy, D- Diet, E – Exercise, GD – general discussion, GE – general education, Mis – Miscellaneous, PS-Problem Solving, R – Relaxation, RP – Relapse Prevention, Ssup – Social Support , ST- skills training) **Measures** (BDI – Beck Depression Inventory, BRFSS – Behavioural Risk Factor Surveillance System, CES-D – Center for Epidemiologic Studies – Depression scale, DASI – Duke Activity Status Index, DKS – Diabetes Knowledge Scale, DAS – Diabetes Attitude Scale, DCP- Diabetes Care Profile, DQOL – diabetes quality of life questionnaire, DSS – Diabetes Support Scale, DHS – Diabetes Health Status ,EDE – Eating Disorders examination, EDI – Eating Disorders Inventory, FHQ – Food Habits Questionnaire, GISED – Gruppo di Studio per l'Educaziione sul Diabetes , GSI - General Severity Index, GHQ – General Health Questionnaire, GDS – Geriatric Depression Scale, HPS – Health Practices Survey , Kristal FFB – Kristal Fat and Fiber Behaviour Scale, Kristal FHQ – Kristal Food Habits Questionnaire, METS – evaluation of energy expenditure, M& SWB – Mental and Social Well Being, MDRTKQ – Michigan Diabetes Research and Training Knowledge Questionnaire, MHLC – multidimensional health locus of control, NCI Block – Block/NCI Fat screener, PAID – Problem Areas in Diabetes, PASE – Physical Activity Scale for the Elderly, PSS – Perceived Stress Scale, PRQ – Personal Resources questionnaire, PESOP – Pleasant Events Scale Older People, QSD – Questionnaire on Stress in Diabetes, SF-36 Short Form 36, STAI – Spielberger State-Trait Anxiety Inventory, ,WBQ – Well Being Questionnaire, WHOQoL BREF – world health organisation quality of life questionnaire, brief)

In tables 3.1 and 3.2 a finding was considered significant if $p<0.05$. Where a controlled trial was conducted results are reported as comparison between groups. Where no comparison group was available or two self-management interventions were compared results are reported within group as comparison from baseline.

3.4.1 Impact of SMIs on Behaviour

SMIs are believed to act at least partly through the impact they have on self-management behaviours. It is important therefore that behaviours are evaluated when assessing the efficacy of interventions. Commonly studies assess the regimen behaviours separately, although some studies such as those by Trento *et al.,* (2004); Garcia *et al.,* (1996); Wierenga, (1994), and Maxwell *et al.,* (1992) have used composite measures, the first three of which found positive effects of the intervention. Given the small number of studies using composite measures, behaviours will be reviewed independently.

3.4.1.1. *Diet* - The most frequently measured self-management behaviour was diet, included in 19 studies. This was typically measured either by a self-report questionnaire e.g. Kristal Fat and Fiber Behavior Scale (Kristal, Shattuck & Henry, 1990), patient recall or by food diaries completed by patients and evaluated for energy intake and consumption of food groups. Overall it would appear that SMIs have a positive effect on dietary behaviour as 12 studies demonstrated beneficial effects. This is similar to the findings of previous reviews (Norris *et al.,* 2001).

Interventions based explicitly or implicitly on social cognitive or cognitive models (see Glasgow *et al.,* 2003, 1992; Kenardy *et al.,* 2002; Vazquez *et al.,* 1998; Agurs Collins *et al.,* 1997; Campbell *et al.,* 1990) were associated with positive effects. In addition interventions based on behavioural weight loss programmes (Guare *et al.,* 1995; Wing *et al.,* 1991a,b, 1988, 1986) showed efficacy. One intervention that included

only education and skills training showed efficacy (Anderson-Loftin *et al.,* 2002), although other similar interventions did not (Laitinen *et al.,* 1993; Falkenberg *et al.,* 1986). Studies that did not show beneficial effects, perhaps not surprisingly, were those where diet was not a focus of the intervention such as a stress management intervention (Surwit *et al.,* 2002) or an exercise intervention (Samaras *et al.,,* 1997). Some studies compared more than one SMI in the same study and indicated that addition of social support (Glasgow *et al.,* 2003; Wing *et al.,* 1991b), community resources (Glasgow *et al.,* 2002), or education in use of SMBG (Wing *et al.,* 1988) did not enhance improvement in dietary behaviour when added to an original SMI.

The findings in studies with a mixed population reflected similar patterns, with those based on social cognitive approaches showing efficacy (Jones *et al.,* 2003; Peyrot & Rubin, 1997; Glasgow *et al.,* 1997), whilst a basic support group intervention did not show benefits compared to education control (Maxwell *et al.,* 1992).

3.4.1.2 *Exercise* – Fifteen studies evaluated exercise behaviour. Those studies which stated that they were based on either SCT or the TTM tended to show positive results (for example see Tudor-Locke *et al.,* 2002; Kirk *et al.,* 2003; Di Loreto *et al.,* 2003; Agur Collins *et al.,* 1997; Glasgow *et al.,* 1992). As with dietary behaviour, behavioural weight loss interventions showed significant effects on exercise behaviour (Guare *et al.,* 1995), although exercise was not additionally enhanced by teaching SMBG or social support skills in combination with a behaviour modification intervention (Wing *et al.,* 1988, 1991b respectively). For a couple of studies the results were less clear with only a trend ($p<0.07$) in improved exercise behaviour (Smith *et al.,* 1997) and benefits dependent upon sufficient use of a computer intervention (McKay *et al.,* 2001). Two studies did not show benefits of the intervention on exercise behaviour (Glasgow *et al.,* 2003; Rickheim *et al.,* 2002). These less positive results may however be due to design issues, such as small

numbers of participants completing the intervention (Smith *et al.,* 1997), or mode of delivery of the intervention. Both McKay *et al.,* (2001) and Glasgow *et al.,* (2003) used the internet for delivery and neither found significant improvement relative to control groups.

Other studies which did not have an effect on exercise behaviour were interventions with a high emphasis on stress management (Toobert *et al.,* 2003; Jablon *et al.,* 1997; Surwit *et al.,* 2002), an exercise intervention based on the Precede Proceed Model from the Health Promotion Literature (Samaras *et al.,* 1997), an intervention based on learner activity problem orientation (Falkenberg *et al.,* 1986) and an intervention based on an amalgamation of several different models (Rickheim *et al.,* 2002). Such approaches may therefore be less useful.

Only one study with a mixed population evaluated the impact on exercise (Peyrot & Rubin, 1999) and found a coping skills intervention using cognitive behavioural approaches resulted in significant effects.

3.4.1.3 *SMBG* - Six studies with type 2 individuals (Trento *et al.,* 2004; Fritshe *et al.,* 1999; Smith *et al.,* 1997; Gruesser *et al.,* 1993; Glasgow *et al.,* 1992; Kronsbein *et al.,* 1988) and 2 studies with mixed populations (Jones *et al.,* 2003; Peyrot & Rubin, 1999) assessed SMBG or urine testing. All but one study (Trento *et al.,* 2004) showed beneficial effects either relative to a control group or over time. Efficacy on SMBG does not however appear to be related to the theoretical design of the study as even interventions consisting of mainly skills training and group discussion (Greusser *et al.,* 1993; Kronsbein *et al.,* 1988), were effective.

3.4.1.4 *Smoking* – Even though reduction in smoking is recognised as an important behaviour in diabetes self-management only 2 studies (Trento *et al.,* 2004; Jones *et*

al., 2003) assessed the impact of interventions on this variable. Jones *et al.,* (2003) reported a reduction in smoking following a SMI compared to a control group, whilst Trento *et al.,* (2004) found no differences between control and intervention groups.

3.4.2 Impact of SMIs on Glycaemic Control

Glycaemic control was the most frequently assessed outcome with 54 of 61 studies in table 3.1 and all studies in table 2 including an assessment of this. In all but 6 studies measures of glycated haemoglobin or HbA1c were included. Of the controlled trials in table 3.1, 22 of the 37 studies showed significant improvements relative to either standard treatment or basic education controls. Of those studies that reported pre-post trials, 14 out of 15 studies showed significant improvements at follow-up compared to baseline. For the mixed studies 3 out of 5 controlled trials indicated improvement relative to controls, with one indicating no differences between groups and one not reporting results clearly (Jones *et al.,* 2003). Three of four pre-post trials with a mixed population indicated improvement compared to baseline.

These generally positive outcomes on glycaemic control are in accordance with other systematic reviews (Ellis *et al.,* 2004; Norris *et al.,* 2002a; Norris *et al.,* 2001; Brown *et al.,* 1992). Reviews by Norris *et al.,* (2002a, 2001) and Brown *et al.,* (1992) have however highlighted that the effect of SMIs on glycaemic control diminishes over longer follow-up periods. A number of studies in the current review fitted this pattern (Sakardi & Roseqvist, 2001; Ridgeway *et al.,* 1999; Blonk *et al.,* 1993; Wing *et al.,* 1991; Falkenberg *et al.,* 1986), however it should also be noted that in some more recent studies efficacy on glycaemic control outcomes was only demonstrated after a delayed period (Trento *et al.,* 2004; Surwit *et al.,* 2002; Glasgow *et al.,* 2002; Brown *et al.,* 2002; Lustman *et al.,* 1998). The reason for this is not clear. Studies by Trento *et al.,* (2004) and Brown *et al.,* (2002) were relatively intensive with sessions

ongoing for a long duration, however so were studies by Sakardi & Rosenqvist, (2001) and Ridgeway *et al.,* (1999). Possibly important is the fact that in all the studies where there was a delay in efficacy either a cognitive or problem solving component was included in the intervention. This may suggest that intervention content rather than duration may be a crucial factor.

The question of how the theoretical basis of interventions related to efficacy can usefully be considered for the outcome of glycaemic control given that the majority of studies measured this outcome. The column headed 'Theoretical Basis' in tables 3.1 and 3.2 states the study defined 'theories' that guided intervention development. Some of these 'theories' could more accurately be described as approaches e.g. stress management or cognitive behavioural approaches. In addition some studies did not describe a theoretical influence but the description of study components implied they were using techniques similar to those that would be used if a theoretical orientation was being followed. These factors were therefore taken into account when reviewing the literature.

The theory most frequently stated as guiding interventions was SCT (sometimes defined as self-efficacy theory (Glasgow *et al.,* 2003), or social action theory (Agurs-Collins *et al.*, 1997). Results based on this theory mainly showed benefits of the SMI (Di Loretto *et al.,* 2003; Miller *et al.,* 2002; Glasgow *et al.,* 2002; Agurs-Collins *et al.,* 1997; Smith *et al.,* 1997; Anderson *et al.,* 1995), although there were a couple of exceptions to this (Glasgow *et al.*, 1997, 1992). A social cognitive approach is similar to the patient empowerment approach defined by Feste & Anderson, (1995). Studies that used this latter approach (Type 2 population - Pibernik-Okanovic *et al.,* 2004; Mixed Population - Keers *et al.*, 2004; Anderson *et al.,* 1995) also showed intervention benefits, as did Peyrot & Rubin, (1999) who although describing their intervention as coping skills used similar techniques.

The emphasis in social cognitive and empowerment interventions is to consider the individual as active in their own self-management and intervene by acting on an individual's cognitions and in particular their self-efficacy, hence facilitating improved self-management. Cognitive behavioural approaches are similar in that they specify that individual's cognitions will influence behaviour which together influence feelings. Hence cognitive behavioural techniques (CBT) may include strategies such as cognitive restructuring, problem solving and goal setting which are also commonly used in social cognitive and empowerment interventions. Interventions based on cognitive behavioural techniques included a study by Lustman *et al.,* (1998a), who reported an improvement in blood glucose at 6mths following an intervention that was targeted at individuals with depression. Henry *et al.,* (1997) and Surwit *et al.,* (2002) included CBT approaches in stress management interventions by focussing on cognitions related to stress. Both studies reported significantly improved HbA1c, although in the latter case this was only at the 12 month follow-up. In contrast stress-management interventions with less emphasis on cognitions and more emphasis on behavioural components such as relaxation and biofeedback resulted in largely no change relative to control groups (Jablon *et al.,* 1997; Aikens *et al.,* 1997; Lane *et al.,* 1993).

Other studies reporting use of CBT approaches included those by Campbell *et al.,* 1996, 1990; Heitzman *et al.,* 1987; Kaplan *et al.,* 1987; Welch, 1992). The first three of these did not report significant improvement in glycaemic control while the studies by Kaplan *et al.,* (1987) and Welch, (1992) did. Both of these latter two studies combined cognitive approaches with behaviour modification and exercise or diet interventions. These are similar to a number of studies that have described their approach as behaviour modification (Ridgeway *et al.,* 1999; Calle Pascual *et al.,* 1992; Pascale *et al.,* 1995; Blonk *et al.,* 1993; Marcus *et al.,* 1992; Wing *et al.,*

1991,1986). Although such interventions have consistently shown improvements over time (for example Calle Pascual *et al.,* 1992; Pascale *et al.,* 1995; Wing *et al.,* 1991, 1988) there is limited evidence on efficacy relative to control groups, as the comparison group in a number of studies has been a further behaviour modification intervention. Exceptions to this are studies by Ridgeway *et al.,* (1999) and Blonk *et al.,* (1993). Ridgeway *et al.,* (1999) reported no significant difference in glycaemic control relative to a control group whilst Blonk *et al.,* (1993) reported significantly better glycaemic control relative to the standard treatment control group at 6 months follow-up. Blonk *et al.,* (1993) included both cognitive and behavioural components whilst Ridgeway relied on only behavioural components in their intervention. It may be, therefore, that the combination of cognitive and behavioural techniques rather than either alone has greatest effect.

A theory that has become increasingly popular in recent years is the TTM. In two studies with type 2 participants an intervention based on the TTM was associated with improvement in glyceamic control relative to a control group (Kirk *et al.,* 2003) and compared to baseline (Rickheim *et al.,* 2002). Jones *et al.,* (2003) also applied this theory but benefit on glycaemic control was unclear for this study.

Interventions have been based on other theories for example the Precede-Proceed Model (Samaras *et al.,* 1997), Reference Group Theory (White *et al.,* 1986) and the Health Belief Model (Wooldridge *et al.,* 1992), however these were not of sufficient frequency to allow for conclusions to be drawn on the association of these theories to effect on glycaemic control.

Of the studies which did not specify a theoretical model or approach, interventions could be classified into those which were comprised largely of general education, discussion and skills training, and others which included behavioural or problem

solving components. Those which included behavioural or problem solving components tended to show significant improvements relative to control groups (Trento *et al.,* 2004; Brown *et al.,* 1999; D'Eramo Melkus *et al.,* 1992; Falkenberg *et al.,* 1986; Mazucca *et al.,* 1986) whilst the discussion and skills training interventions tended not to (Muchmore *et al.,* 1994; Laitenen *et al.,* 1993; Maxwell *et al.,* 1992; White *et al.,* 1986). Hence it appears that even if a specific psychological theory is not specified the use of cognitive and behavioural components in interventions is associated with greater efficacy. Similar conclusions have been suggested by previous reviews. Ellis *et al.,* (2004) in a review of interventions for individuals with type 1 or type 2 diabetes reported interventions, which included cognitive reframing teaching methods as more likely to improve glycaemic control. Norris *et al.,* (2001) reported that more collaborative interventions were more effective than didactic interventions and Griffin *et al.,* (1998) reported larger effects for interventions with behavioural, social learning and patient-centred approaches than didactic approaches.

3.4.3 Impact of SMIs on Blood Pressure

Thirteen studies evaluated the impact of SMIs on blood pressure. Nine of these reported comparison to control groups whilst four reported changes over time. For systolic blood pressure (SBP) no significant differences were seen between intervention and control groups at follow-up in seven studies (Trento *et al.,* 2004; Toobert *et al.,* 2004; Goldhaber *et al.,* 2003; Blonk *et al.,* 1993; Agurs Collins *et al.,* 1997; Campbell *et al.,* 1996; Pieber *et al.,* 1995). Improvement relative to baseline was reported for three studies Tudor-Locke *et al.,* (2002); Calle-Pascual *et al.,* (1992); Wing *et al.,* (1986), although one study found no such improvement (Fritsche *et al.,* 1999). For diastolic blood pressure (DBP) five studies reported no significant differences compared to control groups (Trento *et al.,* 2004; Toobert *et al.,* 2004; Goldhaber *et al.,* 2003; Kirk *et al.,* 2003; Blonk *et al.,* 1993) although four studies did

report some benefit of the SMI (Mazucca *et al.,* 1986; Agurs-Collins *et al.,* 1997; Campbell *et al.,* 1996; Pieber *et al.,* 1995) additionally the study by Calle-Pascual *et al.,* (1992) reported improvement over time.

Overall the impact of SMIs on blood pressure is unclear, although it would appear that DBP is more likely to be positively affected than SBP. Other reviews of the literature have reported similarly mixed findings for blood pressure as an outcome (Loveman *et al.,* 2003; Norris *et al.,* 2001). In addition the type of intervention associated with positive or negative outcomes is unclear and additional studies in the future will need to assess blood pressure to elucidate this.

3.4.4 Impact of SMIs on Quality of Life

Rubin and Peyrot, (1999) have described QoL as 'representing the ultimate goal of all health interventions'. The impact of SMIs on QoL in diabetes is important as increases in self-management behaviours may be hypothesised to lead to reductions in QoL due to increased demands. Alternatively QoL may be increased from the greater sense of control and improved glycaemic control that can be hypothesised to follow SMIs.

Fourteen studies recruiting a type 2 population assessed QoL, the majority (71%) of which were reported in the last 5 years. Results of studies were mixed with some finding evidence of improved QoL (e.g. Trento *et al.,* 2004; Pibernik-Okanovic *et al.,* 2004; Kirk *et al.,* 2003; Rickheim *et al.,* 2002; Kaplan *et al.,* 1987; Basa & McLeod, 1986; Glasgow *et al.,* 2002; Kenardy *et al.,* 2002) and others reporting no benefits following SMIs (Toobert *et al.,* 2003; Surwit *et al.,* 2002; Keyserling *et al.,* 2002; Ridgeway *et al.,* 1999; Wierenga 1994; Muchmore *et al.,* 1994; Glasgow *et al.,* 1992). Studies recruiting a mixed population showed similar findings with some reporting improved QoL (Keers *et al.,* 2004; Gilden *et al.,* 1992), whilst others

reported no benefits following a SMI (Glasgow *et al.,* 1992; Anderson *et al.,* 1995). It should be noted that studies identified here as having a positive effect may have only influenced one out of several aspects of QoL (Keers *et al.,* 2004; Kirk *et al.,* 2003), and hence may be reflecting an overly optimistic picture. It is important to observe however that no studies reported a deterioration in QoL following an intervention. There is therefore no evidence to support the hypothesis that SMIs have a detrimental effect on QoL.

There was some evidence that 'mental' aspects of QoL were influenced more favourably than physical aspects of QoL. Studies by Kirk *et al.,* (2003); Pibernik-Okanovic *et al.,* (2004) and Rickheim *et al.,* (2002) all reported benefits on the mental or psychological sub-scales but not the physical health sub-scales of the QoL measures used.

It is difficult to connect improvement in QoL to the theoretical basis or content of an intervention due to the relatively small number of studies assessing QoL, and in some cases the conflicting results when interventions were theoretically similar. For example of two patient empowerment interventions one reported beneficial effects, in particular on psychological and social domains of QoL (Pibernik Okanovic *et al.,* 2004) whilst the other found little benefit except on reports for change in health (Keers *et al.,* 2004).

The mixed findings reported in this review have also been reported in other reviews (Norris *et al.,* 2001; Steed *et al.,* 2003). The review by Steed *et al.,* (2003) highlighted the importance of measurement tools and their sensitivity to change for assessing interventions. It was noted that the generic SF-36 questionnaire appeared less sensitive to change than diabetes specific assessment tools. The pattern of results seen in tables 3.1 and 3.2 are in line with these conclusions. Further

assessment of QoL with diabetes specific questionnaires is therefore needed to more fully elucidate the impact of SMIs on QoL in type 2 diabetes.

3.4.5 Impact of SMIs on Psychological Well-Being

The aspects of psychological well-being most frequently assessed following SMIs were depression and anxiety. Only one study (Kirk *et al.,* 2001) assessed positive well-being, but did not find improvement in the intervention group relative to the control group. The lack of studies evaluating positive well-being is a gap in the literature as it is possible that SMIs may impact on positive well-being as well as negative well-being.

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3.4.5.1 Depression – Eight studies included in table 3.1 assessed the impact of SMIs on depression. Five studies reported comparisons to a control group, 2 of which reported significant improvement relative to standard treatment or education controls (Lustman *et al.,* 1998a; Henry *et al.,* 1997), whilst 3 reported no significant differences compared to information only control groups (Glasgow *et al.,* 2003; McKay *et al.,* 2002; Glasgow *et al.,* 1992). Both of the studies that reported improvement relative to a control group (Lustman *et al.,* 1998a; Henry *et al.,* 1997), used CBT and targeted mood as a focus of the intervention. Three further studies (Guare *et al.,* 1995; Marcus *et al.,* 1992; Wing *et al.,* 1986) reported significant improvement over time following a behaviour modification weight loss intervention. Two studies with mixed populations also reported beneficial effects on depression. One of these used a coping skills training intervention and found benefits at follow-up compared to baseline (Peyrot & Rubin, 1999), and one reported benefits of a support group intervention compared to education or standard treatment controls (Gilden *et al.,* 1992). One further study with a mixed population did not report efficacy on depression following a coping intervention (Zettler *et al.,*1995).

It would appear that SMIs can have a positive effect on depression, particularly when CBT is used or when mood is a focus of the intervention. A similar conclusion has been made in a systematic review that assessed the impact of diabetes interventions on psychological outcomes (Steed *et al.,* 2003). This review highlights that the efficacy of an intervention is likely to be influenced by the baseline characteristics of the population under examination. Therefore if depression is the outcome of interest, the higher the baseline levels are in the population under study, the easier it will be to demonstrate efficacy of the intervention on this outcome. In both the studies by Lustman *et al.,* (1998a) and Henry *et al.,* (1997) baseline depression scores were high, possibly contributing to the efficacy demonstrated by these interventions.

3.4.5.2 Anxiety – Only five studies evaluated the impact of a SMI on anxiety. Four of these were RCTs of which three (Surwit *et al.,* 2002; Jablon *et al.,* 1997; Aikens *et al.,* 1997) reported no significant benefits of the SMI compared to the control group. These three interventions were specific relaxation interventions aimed to reduce stress and anxiety. One controlled trial (Henry *et al.,* 1997) and one pre-post trial using a mixed population (Peyrot & Rubin, 1999) reported improvements in anxiety and were based on cognitive behavioural approaches or SCT respectively. With such small numbers of studies it is difficult to draw conclusions as to the impact of SMIs on anxiety but it would appear that relaxation training alone is insufficient to improve anxiety.

3.4.6 The Impact of SMIs on Process Variables

To understand SMIs it is not only important to evaluate efficacy on outcomes but also to examine the process of change through which any benefits may have occurred. This can be done by firstly an assessment of whether SMIs influence variables hypothesised to mediate or reflect the change process.

In defining a process variable there is an inherent difficulty in that a construct can often be conceived of as either an outcome or a process measure dependent on context. For example self-management behaviours could be considered an outcome of an intervention but could also be considered as a mediating variable for improvement in glycaemic control, QoL etc. In the current review variables that were considered process or mediating variables were those that derived from the theoretical basis or approach used in the intervention. Self-management behaviours were therefore considered as outcome variables rather than process variables. If only one study measured a process measure e.g. problem solving (Glasgow *et al.,* 1992), self-esteem (Peyrot & Rubin, 1999) results were not reported as this was insufficient for conclusions to be drawn from.

3.4.6.1 *Knowledge* - Knowledge was the most frequently evaluated process measure, assessed in eighteen studies in tables 3.1 and 3.2. The majority of these studies (88%) reported benefits of SMIs, as has been reported in previous reviews (Norris *et al.,* 2001; Griffin *et al.,* 1998; Brown 1992; Padgett *et al.,* 1988). It is well accepted however that whilst knowledge is necessary for self-management it is not always sufficient (Coates & Boare, 1996), therefore examination of other process or mediating variables is important.

3.4.6.2 *Self-Efficacy* – The concept of self-efficacy derives from SCT, which has been used frequently in diabetes SMIs. However, only four studies, two with a type 2 sample (Glasgow *et al.,* 2002, 1992) and two with mixed samples (Peyrot & Rubin, 1999; Anderson *et al.,* 1995) assessed self-efficacy. Three of these studies indicated benefits of the intervention, all of which used an empowerment/social cognitive based intervention (Glasgow *et al.,* 2002; Peyrot & Rubin, 1999; Anderson *et al.,* 1995). It is of note that in the study by Glasgow *et al.,* (2002) effects on self-efficacy only became apparent at 12 months, suggesting that change in self-efficacy may be

delayed, possibly until after behaviour change has been undertaken and performed successfully. Such a hypothesis may explain why no benefits of the intervention were seen in the study by Glasgow *et al.,* (1992), however further studies are needed to evaluate this outcome and test this hypothesis.

3.4.6.3 *Illness Cognitions* - A process variable that is common to a number of different theoretical models including social cognition models is an individual's illness beliefs or cognitions. The extent that these have been measured is limited. A study by Wooldridge *et al.,* (1992), using a mixed sample, aimed to specifically modify diabetes related beliefs by nurse intervention, found significant improvements in beliefs relating to perceived severity of diabetes, benefits of treatment and ability to carry out recommended activities. Benefits of a SMI have also been reported by (Anderson *et al.,* 1995), who demonstrated a decrease in negative attitude and perceived impact of diabetes, relative to a control group, following a patient empowerment intervention. In contrast Brown *et al.,* (2002) found no difference in beliefs relating to control over the effects of diabetes, barriers to diet and taking medications, social support for diet, impact of job on therapy or benefits of therapy when compared to a control group. No studies identified in the current review assessed illness representations as derived from SRM.

Another specific illness cognition that had been measured was health locus of control. Three studies had assessed this (D'Eramo Melkus *et al.,* 1992; Keers *et al.,* 2004; Maxwell *et al.,* 1992). All three studies used the Multidimensional Health Locus of Control Scale (Wallston, Wallston & DeVellis, 1978). Keers *et al.,* (2004) reported that following a patient empowerment intervention participants had a greater belief in internal control and less belief in control by powerful others. Neither the study by D'Eramo Melkus *et al.,* (1992) or Maxwell *et al.,* (1992) however found change following relatively basic education and support groups. To the extent that

internal locus of control reflects an individual's belief in their own abilities to control their diabetes and self-management activities, similarities can be seen with self-efficacy. It may be important that empowerment interventions have had positive effects with both of these process measures, suggesting that this may be a useful approach.

3.4.6.4 *Readiness to Change* – An individual's RTC a behaviour derives from the TTM. Two studies have evaluated this construct (Kirk *et al.,* 2003; Jones *et al.,* 2003) and both found SMIs to assist participants in moving along the stage of change as compared to control groups.

3.4.6.5 *Social Support* – Four studies assessed the impact of SMIs on social support (Glasgow *et al.,* 2003; Pratt & Wilson, 1987; Wierenga, 1994; Gilden *et al.,* 1992). Three of these specifically aimed to evaluate the effect of a social support component e.g. support group (Glasgow *et al.,* 2003; Pratt & Wilson, 1987; Gilden *et al.,* 1992). In two studies individuals who received the support component reported higher social support than individuals without this component (Glasgow *et al.,* 2003; Pratt & Wilson 1987) suggesting that interventions directly targeting support may be effective. In the study by Gilden *et al.,* (1992) however, although family involvement was reported to be higher amongst individuals attending a support group than in the usual care control group, individuals who received just an education programme without an additional support group component reported the highest level of family involvement. The reasons for this are unclear but it should be noted that family involvement assesses only one aspect of social support. It may be that families become less involved in support if they know it is being received from other avenues e.g. a specific support group.

One other study assessed social support, but found no benefits following a behaviour modification group programme compared to a usual care control group (Wierenga, 1994). This suggests that simple presence in a group programme may not be sufficient to improve social support, which requires more direct targeting in the intervention for efficacy.

3.4.6.6. *Stress* – Assessment of perceived stress follows from theoretical models that view stress as impeding diabetes outcomes either through direct physiological effects that impact on glycaemic control, or by a behavioural route where stress impedes self-management behaviours and subsequent health outcomes. In either case it is hypothesised that improved management of stress would be beneficial. Two stress management programmes teaching both progressive relaxation and CBT for coping with stress produced conflicting results. Surwit *et al.,* (2002) reported no benefits but Henry *et al.,* (1997) showed improvement relative to a control group. It may be important that the sample in the latter study were selected because of high stress levels. Two other studies reported improvement in perceived stress following i) a self-management and social support programme (Gilden *et al.,* 1992), with benefits apparent at 2 years post-intervention, and ii) an intervention for coping with fear of complications which reduced stress with respect to fear of complications, acceptance of diabetes and work (Zettler *et al.,* 1995). It would appear therefore that SMIs can have a beneficial impact on stress.

3.4.7 The Association Between Change in Process and Change in Outcome Variables

Although a SMI must have an impact on a process variable for this to be a possible mechanism through which the intervention is acting, an additional association between change in the process variable and change in outcomes is required if the process variable is to be considered a mediator. Therefore, if both self-efficacy and

exercise behaviour increased following an intervention, but there was no association between change in each of these variables, then it would be unlikely that self-efficacy was mediating the change in behaviour. An examination of association between change in process and outcome variables is therefore important when exploring what mechanisms an intervention is acting through.

Only three studies conducted correlation analysis of change between variables (Di Loretto *et al.,* 2003; Lustman *et al.,* 1998b, Kaplan *et al.,* 1987). These studies reported that increased energy expenditure was associated with improved glycaemic control (Di Loretto *et al.,* 2003), remission of depression was associated with improved glycaemic control (Lustman *et al.,* 1998b) and improvement in QoL was associated with improved glycaemic control (Kaplan *et al.,* 1987). In addition one study reported that a reduced belief in chance locus of control predicted increases in physical functioning, whilst increased belief in internal locus of control predicted greater change in health change beliefs (Keers *et al.,* 2004).

To identify whether process variables mediate the effect of the intervention on outcomes formal mediation analysis or path analysis should be conducted. This is important as i) it allows for testing of the theoretical model on which an intervention is based; ii) it allows for identification of effective and ineffective mediators of the intervention; iii) it can lead to improved interventions by targeting important mediators (Baranowski, Anderson & Carmack, 1998; MacKinnon, 1994). Keers *et al.,* (2004) was the only intervention to conduct formal mediation analysis. Future studies should therefore be encouraged to conduct such analysis.

3.4.8 Predictors of Outcomes Following SMIs

When evaluating the efficacy of SMIs consideration should also be given to whether the intervention is equally beneficial to all individuals or whether certain

individuals acquire greater benefit than others. This is termed predictor analysis and can be analysed through correlation and multiple regression. Fourteen of the studies reviewed in tables 3.1 & 3.2 conducted predictor analysis.

The majority of studies examined whether predictors for change in glycaemic control could be identified. Demographic variables did not appear to be robust predictors of change in glycaemic control with studies reporting no association between change in HbA1c and age (Sakardi & Rosenqvist, 2001; Glasgow *et al.,* 1997; Agurs-Collins *et al.,* 1997), gender (Sakardi & Rosenqvist, 2001; Agurs Collins *et al.,* 1997; Boehm *et al.,* 1993), educational level (Sakardi & Rosenqvist, 2001; Glasgow *et al.,* 1997; Agurs-Collins *et al.,* 1997), marital status (Sakardi & Rosenqvist, 2001; Agurs-Collins *et al.,* 1997) or employment status (Agurs-Collins *et al.,* 1997). Two exceptions to this pattern however were a study by Pibernik-Okanovic *et al.,* (2004) who reported that higher educational level predicted change in HbA1c, and a study by Boehm *et al.,* (1993) who reported that increased age and employment were associated with less change in glycosylated haemoglobin.

Clinical variables also appeared to be weak predictors of change in glycaemic control with no prediction found for duration of diabetes (Sakardi & Rosenqvist, 2001; Muchmore *et al.,* 1994; Glasgow *et al.,* 1997), type of treatment (Sakardi & Rosenqvist 2001; Glasgow *et al.,* 1997) or number of co-morbid diseases (Glasgow *et al.,* 1997). Baseline HbA1c was however found to be a significant predictor of subsequent change in HbA1c in four studies (Keers *et al.,* 2004; Pibernik-Okanovic *et al.,* 2004; Sakardi & Rosenqvist, 2001; Agurs Collins *et al.,* 1997) although two further studies did not find this association (Jablon *et al.,* 1997; Muchmore *et al.,* 1994). Other predictor variables including self-management behaviours (Agurs-Collins *et al.,* 1997; Muchmore *et al.,* 1994), anxiety (Surwit *et al.,* 2002; Jablon *et al.,* 1997; Lane *et al.,* 1993) and knowledge (Agurs-Collins *et al.,* 1997) did not predict

change in glycaemic control. Illness cognitions present a more complex picture with cognitions predictive in some studies (see Pibernik-Okanovic *et al.,* 2004) but not others (see Glasgow *et al.,* 1997; Pratt & Wilson, 1987).

Prediction of outcomes other than glycaemic control has been rare with only three studies examining this (Keers *et al.,* 2004; Glasgow *et al.,* 1997; Lustman *et al.,* 1998b). Keers *et al.,* (2004) reported QoL following a patient empowerment intervention to be predicted by baseline QoL, although physical functioning was also predicted by age (Keers *et al.,* 2004). Glasgow *et al.,* (1997) explored predictors of change in food habits following a brief office based intervention (Glasgow *et al.,* 1997) and reported improvement in food habits to be associated with the perceived importance of self-management behaviours at baseline (Glasgow *et al.,* 1997). Thirdly, Lustman *et al.,* (1998b) reported remission of depression following a CBT intervention to be predicted by more frequent compliance to SMBG, less complications, lower weight, and not having a previous history of treatment for depression at baseline (Lustman *et al.,* 1998b). These studies indicate that predictors of benefits following self-management interventions can be identified, and therefore this form of analysis should be encouraged in future evaluations of SMIs in type 2 diabetes.

3.4.9 Methodological Characteristics of the Studies

Analysis of the studies presented in tables 3.1 and 3.2 provide an indicator of the efficacy of SMIs on a range of outcomes, as well as limited evidence on mechanisms of change and predictors of efficacy following SMIs. In reviewing these studies however it is important to highlight the methodological strengths and weaknesses of studies. An important limitation of many studies is the poor description of interventions, in particular in the description of the intervention and its theoretical basis. This makes it difficult to evaluate exactly what type of intervention is taking

place and inhibits replication of the intervention in the future. This criticism of interventions has been made in previous reviews (Griffin *et al.,* 1998; Brown *et al.,* 1999) and the suggestion has been made that studies should publish separate intervention descriptions particularly if space is limited in journal publications (Brown *et al.,* 1999). It has also been commented that descriptions of care in the control group is inadequate in many studies (Norris *et al.,* 2002b). An understanding of control group care is important given that what constitutes routine care is likely to differ both between studies and over time.

A common criticism of studies of SMIs in previous reviews has been that small sample sizes lead to insufficient power to detect effects (Griffin *et al.,* 1998; Padgett *et al.,* 1988). It has been calculated that for a study to achieve 95% power, based on a 0.9% change in HbA1c, then 55 participants per group would be necessary (Kronsbein *et al.,* 1998). In total only 24 out of the 69 studies presented here had sample sizes sufficient to achieve this level of power. Improvement has been made in the last 5 years however, with 13 out of 23 (57%) studies now achieving sufficient power as compared to 11 out of 46 (24%) studies, pre 1999. Inadequate power however remains a problem for many studies, particularly when it is considered that attrition either from the intervention or follow-up assessment is common. Attrition from an intervention is infrequently reported but can be an important indicator of satisfaction with the intervention. This has been highlighted by a study that compared intervention groups receiving either individual education, group education or a behavioural programme (Campbell *et al.,* 1990). At three months follow-up attrition from the individual intervention was 18%, from the group programme was 21% but from the behavioural intervention was only 4%. This reflects far greater satisfaction with behavioural as compared to either individual or group education, an important finding in its own right.

The outcomes assessed in studies are important to consider. Whilst the majority of studies assess glycaemic control, far fewer assess QoL or psychological well-being. There is also inconsistency in the extent that process measures are assessed, which as has been highlighted, is key to determining the mechanism through which interventions are working.

The measurement tools selected are also important as these may influence apparent efficacy of the intervention. For certain outcomes e.g. glycaemic control a gold standard measure (HbA1c) has become accepted. Measurement is however more problematic with other outcomes such as behaviour. Many assessments of behaviour have relied on self-report or diary measures. Such measures have been criticised as open to participant bias and hence some studies have begun to include more objective measures of behaviour for example accelorometers /pedometers to measure exercise, or lipid profiles etc to reflect diet. Self-report measures are often selected because of their low cost and ease of use, however their limitations need to be taken into account when evaluating studies.

The extent that developed interventions have been guided by prior evidence is also limited. An exception to this is the work from Wing and colleagues in Pittsburgh, USA that has consistently compared behaviour modification interventions manipulating only one aspect of the intervention at a time. Future studies should be modelled on this work to try and elucidate the components, or populations, for which SMIs are most beneficial. In doing this it may be valuable to consider the role of factors that have been relatively neglected in SMIs to date. One such factor is the teaching of social support skills. The potential importance of social support in successful self-management and for both clinical and psychosocial outcomes was discussed in chapter 2. Surprisingly however, only one study (Wing *et al.,* 1991b) has aimed to directly manipulate this by teaching participants social support skills. Some

interventions have aimed to address the issue of social support by designing group discussion or 'support' sessions, however this is conceptually different from teaching individuals specific skills such as communication skills.

3.5 Strengths and Weaknesses of the Current Review

Although limitations of individual studies must be recognised it is also important to consider the limitations of the review itself. The current review may be criticised for including only published, peer reviewed studies. This inclusion criteria was set for both practical reasons i.e. limiting the volume of literature to be reviewed, and as an attempt to ensure studies of methodologically high quality were included. Limiting a review to include only published studies does however incur the risk of publication bias whereby studies which are significant are more likely to be published than non-significant studies.

A further limitation of the current review is the selection of only certain outcomes. It is acknowledged that important outcomes such as weight loss, body mass index, blood lipids etc. were not included in the review. These outcomes were excluded in part to ensure the review was focussed to the interests of the current thesis and also because systematic reviews of these outcomes have already been conducted (see Brown *et al.,* 1996).

Although the current review has limitations it also has strengths in that both pre-post and randomised controlled trials were included. This gives a more comprehensive overview of studies than in some previous reviews e.g. Loveman *et al.,* (2003); Ellis *et al.,* (2004); Corabian & Harstall, (2001). In addition the current review assessed a range of outcomes and also attempted to associate outcome to theoretical basis, which has been done in only a minority of previous reviews (see Norris *et al.,* 2001; Griffin *et al.,* 1998).

3.6 Conclusions and Practice Recommendations From Systematic Review

The findings of the current literature review, together with findings from previously published reviews, suggest that SMIs can lead to a range of benefits on clinical, behavioural and psychosocial outcomes in type 2 diabetes. Future studies however need to be of adequate size with detailed descriptions of the intervention provided. Interventions should be theory driven with SCT of particular use. Greater consideration should also be given to determining the mechanisms through which change occurs in SMIs. This can be done by increased assessment of process measures and appropriate statistical analysis of such variables.

Analysis of predictor variables should also be given greater precedence in studies. It is currently unclear whether a one size fits all approach can be used successfully for diabetes self-management, or whether a more selective model is useful.

Additional SMIs also need to be completed outside of the USA. Few studies have been published in Europe and Britain specifically, although a Diabetes UK report (Naqib, 2002) has stated that there are a number of ongoing studies in the UK. Although it might be hypothesised that interventions may translate from the USA to the UK this cannot be assumed, particularly in areas of the UK where the population is culturally diverse. The need for additional SMIs within the UK is also supported by the National Service Framework for Diabetes in the UK (Department of Health, 2001). This framework encourages self-management as a central part of care for all individuals with diabetes. Evaluation and publication of UK studies should therefore be another target of research.

3.7 Aims of the Current Study

In line with the above recommendations the current study was designed to address a number of aims as detailed below:

i) To develop a self-management intervention for people with type 2 diabetes drawing on Bandura's Social Cognitive Theory and Leventhal's Self-Regulation Model.

ii) To develop a second intervention based upon that described in i) but with the addition of social support skills teaching.

iii) To describe both interventions in detailed manuals which would ensure consistency in implementation of the interventions and replication or review in the future.

iv) To evaluate both interventions in relation to a standard treatment control group using a part-randomised patient preference trial.

v) To evaluate the interventions and control group on clinical, and psychosocial outcomes at four time points, pre intervention, immediately post-intervention, 3 months post-intervention and 9 month post-intervention.

vi) To evaluate a range of process measures drawn from social cognitive theory and the self-regulation model and consider the role that these play in mediating change in the primary outcomes.

vii) To explore the role of individual differences in predicting those individuals who demonstrate greatest benefits from the interventions.

viii) To explore the relationship between self-management behaviours, glycaemic control and quality of life.

Related to the above aims of the study a number of hypothesise were specified a priori:

i) Individuals attending a self-management intervention will demonstrate greater improvement on self-management behaviours, glycaemic control and quality of life than the control group.

ii) Individuals attending a self-management intervention with social support skills training will demonstrate greater improvement on self-management behaviours, glycaemic control and quality of life than the control group but will additionally demonstrate greater efficacy on the measured outcomes than the standard intervention group.

iii) The mechanism of change facilitating improvement in self-management behaviours from baseline to post-intervention will be mediated by self-efficacy and an individual's personal models of diabetes in accordance with social cognitive theory (SCT) and the self-regulation model (SRM).

CHAPTER FOUR: DEVELOPMENT OF SELF-MANAGEMENT INTERVENTIONS AND MANUALS

4.1 Structure of the Chapter

This chapter describes the development of the two SMIs proposed in chapter three. The development of the interventions involved four stages i) review of previous literature, ii) consultation with health care professionals, iii) focus groups and interviews with patients, iv) piloting of each programme. The methods and results of each of these stages are described and an overview of the final versions of the interventions presented. The chapter then describes the training that all health care professionals involved in facilitation of the interventions underwent.

4.2 Review of Previous Literature Reviews

Before developing a new SMI the state of current knowledge about SMIs in type 2 diabetes was established. This firstly involved examination of literature reviews published within the area. The reviews considered included Brown, (1988,1992,1999), Fain *et al.,* (1999), Griffin *et al.,* (1998), Clement, (1995), Goodall & Halford, (1991) and Padgett *et al.,* (1988).

A number of conclusions were presented in the reviews that could be applied to future studies. These conclusions have been categorised into those relating to intervention content and those relating to methodological characteristics of studies.

4.2.1 Intervention Content

1. SMIs in diabetes have positive effects on knowledge and glycaemic control in particular, and the addition of behavioural, social learning and patient-centred

approaches to basic education can increase efficacy (Brown, 1999; Griffin *et al.,* 1998; Clement, 1995; Padgett *et al.,* 1988). Due to the lack of knowledge often identified in patients with diabetes however, education should still be a component of interventions (Brown, 1999).

2. Interventions that are theoretically based e.g. on social learning theory, tend to be associated with larger effect sizes than basic education approaches (Griffin *et al.,* 1998).
3. There is little evidence to indicate that substantive characteristics of studies, e.g. hospital versus community setting, length of programme or group versus individual interventions are differentially associated with outcomes. One exception to this may be age, as younger participants were reported to have greater benefits from interventions than older participants in a review by Brown, (1992).

4.2.2 Methodological Issues

1. Insufficient attention has been given to recruiting representative samples and reporting of attrition from studies (Griffin *et al.,* 1998).
2. Few studies have been conducted outside of the USA (Griffin *et al.,* 1998).
3. Studies have frequently developed new measures for assessment rather than using previously established measures with proven reliability and validity (Griffin *et al.,* 1998).
4. Outcome measures have frequently included knowledge, self-reported diet & exercise and glycaemic control, but not assessed other important outcomes such as illness cognitions, QoL, objective assessments of behaviour and cardiovascular risks (Griffin *et al.,* 1998, Fain *et al.,* 1999).

5. Effects of interventions often deteriorate with time. Mechanisms to address this should therefore be explored (Brown, 1992) e.g. positive reinforcement at regular time points (Clement, 1995). In addition more longitudinal, repeated measures designs should be implemented to assess effects over time (Fain *et al.,* 1999; Padgett *et al.,* 1988).
6. Patients with type 1 and type 2 diabetes have commonly been mixed in the same study limiting understanding for each separate condition (Griffin *et al.,* 1998, Brown, 1999).
7. Interventions are often poorly described in publications (Griffin *et al.,* 1998) and insufficient for replication (Fain *et al.,* 1999). Separate publication of intervention descriptions may therefore be desirable (Brown, 1999).

Previous reviews of the literature have indicated that SMIs are beneficial in type 2 diabetes. In addition they provide a number of helpful recommendations for future studies. However none of the reviews explored the components of SMIs e.g. the techniques that were included or the extent that these influenced efficacy. Although both Griffin *et al.,* (1998) & Padgett *et al.,* (1988) examined the association of theory to efficacy, and found social learning approaches to be particularly beneficial, component analysis would be an extension to this work with the potential to provide important information on what should be included in a SMI.

4.3 A Review of the Components of SMIs

4.3.1 Methods of the Review

To examine the association of intervention components to efficacy a review of SMIs was conducted. This was similar to the review conducted in chapter three with the exceptions that only studies between 1974 and 1999 were included in the current review

and only the outcome of glycaemic control was evaluated. With these two exceptions the methods were identical to those described in section 3.3 of chapter 3. In addition all interventions were coded for components as described below.

4.3.1.1 Coding of Interventions - All groups within studies were coded according to the components described in table 4.1. Two individuals completed coding independently, ratings were then compared and a kappa score of 0.86 was calculated for inter-rater reliability. Where there was not consensus over the components of a study a third individual was asked for their input.

Table 4.1 - Codes of Intervention Components

Code	Component Description
GE	**General Education** -Basic provision of information, commonly using didactic techniques. This code was also used when the only description given was education programme.
GD	**General Discussion** -Discussion between participants within a group. Can be facilitated by professional or lay leaders.
ST	**Skills Training** -Teaching of clinical skills for management of diabetes, studies must make it explicit that this involves practical demonstration by educator, or practice by participants, otherwise this would be coded as general education
B	**Behaviour Therapy** -Use of behavioural techniques such as goal setting, reinforcement, modelling, reward systems, alteration of environmental cues
PS	**Problem Solving** -Identification of problems or barriers to behaviour, and strategies to overcome them. Includes both practical and psychosocial problems. Focus should be on patient problem solving rather than problem solving by health care

	professionals
C	**Cognitive Therapy** -Teaching or use of cognitive techniques to influence cognitions e.g. challenging beliefs, considering role of thoughts and emotions, counselling and psychotherapy. Where the term coping skills was used, and it did not adhere to definition of problem solving above, it was coded as cognitive therapy.
SSup	**Social Support** -Teaching techniques to specifically help participants improve social support e.g. where to go for extra support, communication skills. Simple support groups were not coded as this.
R	**Relaxation** -Actual practice of relaxation, may include imagery or distraction techniques
Bio	**Biofeedback** -Use of biological feedback to assist relaxation
RP	**Relapse Prevention** - Discussion of how to maintain behaviour in the future and prevent relapses.
D	**Diet**- Participants prescribed a specific weight loss plan as part of intervention. Advice on healthy eating diet and related goal setting was not coded.
E	**Exercise** - Specific exercise sessions as part of intervention.
Mis	**Miscellaneous** - Where a term is used but not described in sufficient detail to code as any of the above, e.g. stress management.

Code: GE- General Education, GD – General Discussion, ST- Skills Training, B- Behaviour Therapy, PS-Problem Solving, C- Cognitive Therapy, SSup – Social Support, R – Relaxation, Bio – Biofeedback, RP – Relapse Prevention, D- Diet, E- Exercise, Mis-Miscellaneous

4.3.1.2 Analysis of Intervention Components - Individual components, with the exception of GE,GD,D,E,Mis, were associated with outcomes by calculating the frequency that an individual component was associated with significant improvement, deterioration or no-significant changes in glycaemic control. GE,GD,D,E,Mis components were not considered in the analysis as the inclusion/exclusion criteria meant that the studies

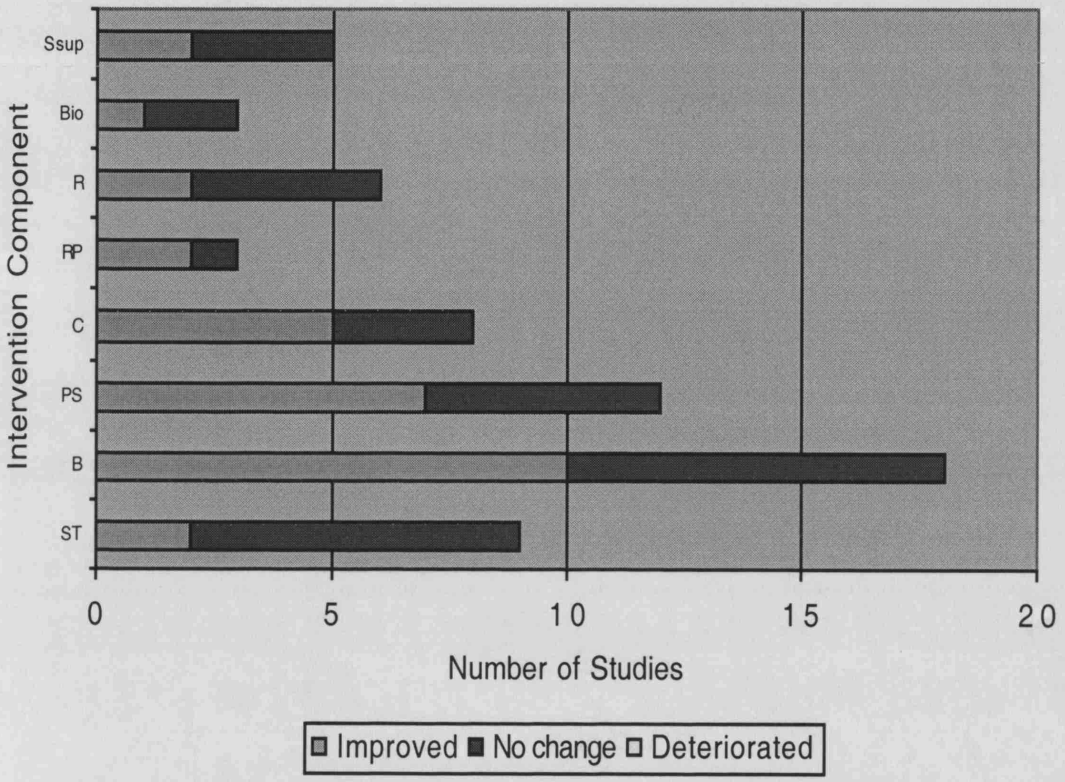
included in this review did not cover all possible interventions incorporating these components, hence the current review may not have provided a fair reflection of the efficacy of these components. A meta-analysis was not performed because of the high degree of heterogeneity in studies. Although all studies can broadly be defined as SMIs their content varies considerably as does the type of patient, number of sessions, duration of sessions etc. A meta-analysis would primarily provide information on whether SMIs as a group impact on glycaemic control, and not how different components relate to outcome. To examine the impact of components on outcome, a more qualitative approach was therefore necessary.

4.3.2 Results of the Review

The studies included in this review are shown in tables 3.1 & 3.2 in chapter three and are all studies prior to the end of 1999, not including those with mixed samples. In total 42 studies that adhered to inclusion/exclusion criteria were identified. Figure 4.1 presents a graph of component efficacy for controlled trials. Behaviour therapy and problem solving were the most frequently included components and both were associated with improvement in glycaemic control in the majority of cases, as was cognitive therapy and relapse prevention. In contrast skills training, relaxation and biofeedback were associated with no change in glycaemic control in the majority of studies. Social support skills were associated with improvement in only two out of five controlled trials however due to poor intervention descriptions it is unclear whether these skills were taught adequately. It could therefore be suggested that inclusion of cognitive, problem solving and behavioural components is preferable to simple skills training or relaxation techniques. When pre-post trials were analysed all components were associated with improvement in glycaemic control. This was true for eight studies examining behaviour therapy and skills training, four studies for problem solving and

cognitive therapy, two studies for relapse prevention, one study for relaxation, none for biofeedback and three for social support. This illustrates the importance of study design in discriminating the efficacy of different intervention components.

Figure 4.1 Efficacy of Intervention Components



4.4 Implications of the Review of Previous Literature

Drawing together the recommendations from previous literature reviews and the review of components of SMIs a number of decisions were made for the development of the current SMI.

1. The programme should be documented in a manual to ensure consistency of delivery and allow for replication and examination in the future.

2. The programme should be theoretically based, and techniques used to assist behaviour change should complement this theoretical basis.
3. The main theoretical basis for the SMI should be SCT (Bandura, 1977, 1986, 1997), and SRM (Leventhal, 1984), although principles from other theories such as the TTM (Prochaska & DiClemente, 1984) should be taken into account where appropriate. For example when an individual sets a goal these should be appropriate for the individual's stage of change.
4. Components that will influence the variables specified in SCT and SRM should be included in the intervention. SCT suggests that self-efficacy can be increased through mastery, vicarious experience and social persuasion. A group environment with encouragement and practice of behaviours, agreed in goal setting could therefore facilitate change in self-efficacy. An individual's RTC should be accounted for by helping the individual set goals at an appropriate level. Goal setting also acts as a form of implementation intention. Other techniques such as problem solving could address barriers to change, and eliciting and challenging beliefs could shape illness cognitions. Inclusion of such components should facilitate improvement in self-management.
5. Where skills are taught such as SMBG, diet selection or insulin injection these should include practical sessions.
6. To build upon previous research, and explore more fully the efficacy of training in social support skills in SMIs, two interventions with and without this component should be compared.
7. To address the poor maintenance of intervention effects found in previous research a booster session at 3 months post-intervention should be included.

4.5 Consultation with Multi-disciplinary Health Care Professionals

A working group was set up to assist in the development of the SMI and manual. This consisted of 2 Health Psychologists, 2 Consultant Diabetologists, 1 Consultant Nephrologist, 1 Diabetes Specialist Nurse, 2 Dieticians, 1 Podiatrist. The task of the group was:

1. To advise on the type of patients to be offered the SMI.
2. To advise on the informational content of the manual, and review drafts of the manual at set periods.
3. To define the current treatment available to normal care patients, including education provision.

4.5.1 Advice on Intervention Participants

Patients with established type 2 diabetes were suggested as a group in need of a SMI. It was reported that this group of patients would not have received group input since initial diagnosis, however many individuals were reported to have difficulty with self-management. In addition, patients with evidence of microalbuminuria or proteinuria were felt to be a group for whom changing health behaviours and improved self-management would be of primary importance, as Microalbuminuria and proteinuria are predictors of the development of micro and macrovascular complications (Gaede, Vedel, Parving & Pedersen, 1999). It was considered that because of the early sign of complications, these patients would also be particularly ready to make behaviour changes. The manual was therefore written keeping the characteristics of these patients in mind.

4.5.2 Advice on Manual Content

Topics for possible inclusion within the intervention were brainstormed by the working group and subsequently prioritised. The topics considered to be the most important to include were:

1. An explanation of what diabetes is and its association with complications, including microalbuminuria and proteinuria.
2. The importance of blood glucose and blood pressure control and their relationship to self-management.
3. What is meant by 'Self-Management'?
4. Home blood glucose monitoring (HBGM)[1] - how and when to measure, the meaning of readings, and the implications of results for adjustments in diet, exercise and medication.
5. Diet – Appropriate content and portion sizes, and the relationship of diet to exercise and hypoglycaemia. Barriers to diet, this was considered to be one of the most important areas to address and it was suggested that it may require more than one session.
6. Exercise - Discussion of what sort of exercises would be suitable for this more elderly population. Association of exercise with hypoglycaemia and how to avoid this. Barriers to exercise.
7. Insulin and Medications - Injection skills, fears of insulin and increasing medications. Barriers to medications.
8. Social or Occupational Issues - The influence of diabetes on an individual's social and working life. Understanding the worries and fears that people with type 2 diabetes might have. It was suggested that these issues should be addressed throughout the programme.

Further consultation with the multidisciplinary group was held on completion of the draft manuals. All members of the group reviewed the drafts and provided feedback, which was incorporated into the final manuals.

4.5.3 Advice on what Comprised Standard Care

Routine care included invitation to a single group education session at the time of diagnosis of type 2 diabetes. Subsequently all individuals received a yearly annual review as a minimum, with as many additional medical consultations as deemed necessary. In addition consultations with diabetes specialist nurses, dieticians or podiatrists were scheduled as required. Education of patients was seen as an integral part of all consultations but was not standardised and primarily took a didactic format.

4.6 Focus Groups

4.6.1 Methods of Focus Groups

Two focus groups of 6 to 8 participants each were planned. One group was to be held in the evening and one in the afternoon. This was to ensure that a cross-section of likely participants for the programme was sampled. The purpose of the focus groups was:

1. To assess whether a SMI would be of interest to patients and whether they felt they would be likely to commit to such an intervention.
2. To confirm whether the topics identified by the multidisciplinary working group for inclusion within the intervention were felt to be relevant by patients.
3. To see whether there were additional topics that patients felt to be important to include in a SMI, which had not been identified by the healthcare professionals.
4. To assess the logistics of offering such an intervention, such as whether partners should be invited, when to run the groups, how long each session should run for etc.

5. To provide a patient perspective on what would make the intervention more or less attractive.

A facilitator and assistant were present at each focus group. The facilitator, the supervisor of the thesis candidate, took responsibility for asking questions and directing discussion. This individual was selected as facilitator because of previous experience in this role. The assistant, the thesis candidate, was responsible for note taking and observation of the group.

Participants for the focus groups were recruited from the Whittington Hospital, London and were provided with an information sheet about what the focus group would involve (see appendix one). Prior to commencing the discussion, all participants were asked for their permission for the session to be tape-recorded. In addition, all participants signed a consent form agreeing to their participation in the focus group (see appendix one). Individuals participating in the focus groups were not included in the final study but were offered the opportunity of receiving the SMI at pilot sessions.

Table 4.2 shows the transcript of questions and prompts used in the focus groups. After a brief introduction a general question relating to behaviour change in diabetes was presented. This was followed by more specific questions about four diabetes self-management behaviours. The discussion was then directed towards more emotional and social aspects of living with diabetes. Finally the concept of a SMI was explicitly presented and participants were probed for their interest in such an intervention and opinions on running such an intervention.

Table 4.2 - Focus Group Questions

Introductions

- Please tell us how long you have had diabetes and what treatment you are on.

Behavioural Questions

- Thinking back to before you were diagnosed with diabetes, are there changes that you have had to make to your life as a result of your diabetes?
- Which of these changes have you found easier/more difficult to make?

Diet

- We would now like to talk about the changes you may have made to your diet.
- Have you found any difficulties making changes to your diet?
- Can you describe what makes it easier/more difficult to follow your diet?

Exercise

- Have you ever been given any advice about exercising? Did you find it difficult or easy to follow this advice?
- What was it that made it difficult or easy to follow this advice?

Self-Monitoring of Blood Glucose

- Do any of you monitor your blood glucose?
- What encourages you to monitor your blood glucose?
- Is there anything that makes it more difficult for you to monitor your blood glucose?

Medications

- For those people taking tablets do you have any concerns about your medications?
- What are they?
- Is there anything that has an influence on whether you decide to take your medication or not?
- Do you think it is likely that there will be changes to your medication in the future?
- What would your thoughts be about going on to insulin e.g. practicalities, fears, self-perception?

Insulin

- For those people already taking insulin how did you feel when you were told you needed insulin?
- Have those feelings changed now that you are taking insulin?
- What advice would you give to someone if they were about to start using insulin?

Fears/ Worries

- Do you have any concerns about your diabetes at present?
- What is your greatest concern about your diabetes as it is at the moment?
- What is your greatest concern about your diabetes for the future?
- Is there anything that would help you deal with these worries or fears more easily e.g. information, more support?

Self-Perception

- How do other people react to your diabetes?
- Does having diabetes influence the way you see yourself?

- Do you feel other people have treated you differently since you were diagnosed?

Social Support

- Are there things that your family or friends do that influence how you look after your diabetes?
- Are there any things your family or friends do that make it harder or easier to cope with your diabetes?

Introduction of Concept of Self-Management Programme

- What would be the most important thing for a self-management programme to include e.g. topics, ways of teaching?
- What would make it more or less likely that you would come to the programme?

Audio-tapes of each discussion were transcribed and used for data analysis. Due to the small amount of data full qualitative analysis was not attempted. Rather the transcripts were scanned for confirmation of the information presented by the multidisciplinary working group, and for additional ideas that would aid the development of the interventions and manuals.

4.6.2 Results of Focus Groups

Focus group one consisted of three male participants with diabetes (P1-P3) and one female partner (P4). For focus group two only one male participant attended (P5). This participant was therefore interviewed individually. An additional female patient (P6) who was unable to attend the second focus group at the last minute also agreed to an individual interview. The thesis candidate conducted both interviews. The small number

of participants taking part in the focus groups was disappointing, however due to time constraints it was not possible to organise further groups.

Caution must be used in deriving conclusions from such a small number of participants. Although the use of two different qualitative methodologies (focus groups and individual interviews) may be beneficial as a method of triangulation, it is clear that more participants within each method would have been desirable and essential for full qualitative analysis. The following informative points were however raised in the transcripts:

- Diet was raised as an area where changes had to be made early on. While most participants reported that it was not difficult participant 6 admitted to some difficulties:

  P5 " It wasn't difficult to make dietary changes just changed to brown rice and brown bread."

  P6 "at first it [diet] was not easy but you get used to it. It was easy because I've never liked fried food but it was difficult because I'm a big eater and I'm not full enough.. still hungry."

  P4 " can I just raise diet? You didn't find that particularly difficult ...but losing, he's got or had a sweet tooth, and we were away at the time and his temper was on a knife-edge. Do you remember? I did notice that with the sudden change in diet.

- Insulin was mentioned as another big behavioural change. There tended to be a consensus that this was initially difficult but that subsequently it had been accepted.

P1 "probably the most difficult thing was using the hypodermic for the first time, but after that it was just a normal impediment to ones normal existence."

P2 " Insulin, said no-way when I was told I would be doing it on a daily basis. I said there was no-way I could be doing that every day. But then I said look it's for my own good, so I could do it."

P3 "Insulin, testing, sticking needle into self was difficult."

P6 " I worried at first about the injections. I thought the act of injecting self was going to be worse than it actually was."

- Taking insulin was an aspect of the regimen that tended not to be neglected however this was in contrast to taking medications e.g. diuretics.
  P6 ' I do take my insulin because you hear so many stories of people losing their legs, their arm, strokes and eyesight. So I make sure I take the insulin"

  P6 " I don't take water tablets because if going out have to keep rushing to the loo ... I say to myself if my blood pressure is stable why am I still on all these tablets. I should be off some or on less dosage to see how it works."

- Exercise was not mentioned until prompted and there was some evidence that individuals found this behaviour difficult.
  P6 " I was told to do brisk walks but I don't ... I do walk a bit. People have a go, make a joke about walking to church."

- All participants monitored blood sugar, although again this was an area of the regimen that was more open to lapses.

  P1 " being busy might be in a meeting and I just wouldn't do it (SMBG), unless I felt there was a problem in which case I'd be likely to go and get something to eat. Testing isn't so necessary unless one felt bad, in which case it is a different point. "

  P6 " I used to do it every day but I got fed up so stopped. It was higher than before so I said leave it for a while."

- Current worries about diabetes related to hypoglycaemia

  P6 " I worry in case I miss medication or going out no-one knows I'm diabetic and I collapse and some-one doesn't know I have diabetes.

- In relation to the SMI participants reported that groups would be a good forum although they would need to be homogenous.

  P6 " In groups is chatting. I'm not a chatty person but I like groups.

- Points to include in an intervention would be the progression of diabetes and the inter-relationship of factors.

  P2 "should be told initially start on a diet, if no improvement of illness then it will be tablets. If it gets out of hand it will be insulin. If I had been told all these things in advance I would have started insulin happily because I would know in advance."

  P1 " 'teaching about the inter-relationship of the various functions of insulin and diet, the impact of being ill and eating too much or eating too little might have. Need a proper understanding of what's going on."

- There were differing opinions on whether partners would be useful at the programme. The fact that there may be cultural issues here was raised.

Analysis of the focus groups and interviews with patients confirmed that individuals with diabetes found some difficulties in carrying out their self-management behaviours and that a group intervention would be a useful way to address these. Additional topics to those raised by the health care professionals were not raised by patients, and hence the topics raised by the working group were concluded as an appropriate core syllabus for the intervention.

4.7 Draft Versions of Interventions and Manuals

Following the initial consultation with health care professionals and patients, draft versions of the standard and social support manuals were written in close collaboration with the diabetes specialist nurse and dieticians. The drafts were then given to the team of health care professionals for their comments. Amendments were combined into a final draft that was used for piloting. The final drafts of the manuals were split into two parts.

4.7.1 Part One - Technique Guides

This section of the manual provided a series of technique guides to complement facilitator training. Guides were provided on:

1. the theoretical principles of behaviour change, on which the intervention was based e.g. SCT and the SRM.

2. the techniques used to facilitate behaviour change which were implemented repeatedly throughout the intervention e.g. brainstorming, goal setting, problem solving.
3. for the social support manual there was also a section on techniques to elicit social support.

4.7.2 Part Two - Intervention and Session Descriptions

This section provided detailed descriptions of each session. The final draft version of the intervention was based on five weekly sessions each lasting 2.5 hours, plus one booster session of 2.5 hours at 3 months. One main facilitator (a primary care nurse) led all sessions. This individual facilitated brainstorming sessions, group discussions, problem solving skills and goal setting in all sessions. In the latter halves of sessions one and four a diabetes specialist nurse also attended and provided informational support and skills training in blood glucose monitoring and medication taking respectively. In session two and the first half of session three a dietician also attended to provide informational support and skills training in relation to diet. All of these professionals underwent the training described below (section 4.9) to ensure their interaction with participants was in a facilitatory rather than didactic manner. Following each session the thesis candidate met with the programme facilitators to debrief on how the session had gone and provide ongoing support and advice in the techniques being used. This aimed to problem solve difficulties and ensure the correct techniques were being implemented.

Table 4.3 shows the time-table for the five sessions. It can be seen that each behaviour was addressed over two consecutive weeks. This was to enable participants to attempt

behaviour change between sessions and report their experiences back to the group the following week. A separate chapter of the manual was dedicated to each session.

Table 4.3 – The Time-Table of the UCL-DSMP

Session One	i) What is Diabetes? ii) What is Self-Management?	*Coffee Break*	iii) Home Blood Glucose Monitoring (HBGM) iv) Goal setting for HBGM
Session Two	i) HBGM - barriers ii) Food and Diabetes	*Coffee Break*	iii) Healthy Eating Principles and Strategies iv) Goal Setting for Healthy Eating
Session Three	i) Healthy Eating - barriers ii) Eating in Social Situations	*Coffee Break*	iii) Benefits of Exercise iv) Barriers to Exercise
Session Four	i) How to Exercise Safely ii) Goal Setting for Exercise	*Coffee Break*	iii) Medication and Diabetes iv) Sick Days and Medication
Session Five	i) Barriers to Medication ii) Difficult Situations	*Coffee Break*	iii) Summary of Problem-Solving iv) Maintaining Goals

Each of the chapters began with a set of objectives that was to be achieved by the end of each session. The manual then specified all the information that should be covered within a session, including how this information should be elicited e.g. brainstorming, probes etc. that might be helpful. Where a practical exercise was to be performed this was indicated within the text and a detailed description of the exercise was given at the end of the chapter. The sessions were designed so that as much of the learning as possible occurred from within the group, and a didactic approach was avoided. The role of the group leaders was as facilitators as opposed to traditional lecturers. Although the purpose of the manual was to ensure consistency between groups it was accepted that different individuals would present different problems, and therefore to an extent discussions within topics may vary. This variability was felt to be acceptable within the boundaries of the objectives stated within the manual, and providing the teaching of problem solving techniques was consistent.

For the social support manual the description of sessions was the same as for the standard intervention but with three key differences:

i) when barriers and solutions to self-management problems were discussed consideration was given to the role of the partner in these situations e.g. how a partner could help or hinder in certain situations.

ii) when goal setting the partners were asked to set a goal of something they could do to support their partner in their respective goal.

iii) feedback at the beginning of sessions looked at whether the behaviours set as goals had been supportive or not. This was complemented with discussion around how to improve communication about supportive behaviours e.g. what is and is not supportive and how and when to indicate the need for support.

4.8 Piloting and Finalising of the Self-Management Interventions

Having developed the final draft versions of the manuals the programmes were piloted with a group of four participants for the standard programme and three couples for the social support intervention. These included 5 individuals who had attended the focus groups and two further volunteers with partners. Feedback from both facilitators and participants was elicited following the interventions and was used to inform the final versions of the interventions and manuals.

4.8.1 Feedback - Standard Intervention and Manual

Participant comments were very positive and no suggestions were made as to how to improve the programme. Facilitator comments were mainly around the time-pressures related to completing topics and exercises within the sessions. The main concern was that diet needed more time than had initially been allocated, and specifically that it was not possible to complete two practical exercises in session two. Facilitators also noted that participants were not always forthcoming about problems with the self-management behaviours covered in the manual, and they sometimes raised issues not covered by the manual e.g. impotence or smoking.

4.8.2 Final version of the Standard Intervention and Manual

The final version of the manual and intervention was amended to take account of the issues raised in piloting (see volume 2 for final version of manual). Subsequent changes were:

- One of the practical exercises involving food models and demonstration of portion sizes originally in session two was moved into session three. Exercise behaviour

was consequently addressed more briefly in session three and returned to more fully in session four.

- Additional prompts were written into the manual, these could be used to encourage participants to disclose problems. It was, however, acknowledged that not all individuals would experience difficulties with behaviour change and this should be accepted.
- It was not felt appropriate to add additional topics into the manual, particularly those that may not have been common to all participants, as there was a concern about addressing too many topics within one programme. It was therefore suggested that topics such as smoking or impotence could be considered in session five under the discussion of difficult situations. These problems could then be used to illustrate the application of problem solving techniques to issues not specifically taught in previous sessions.

The final version of the intervention was labelled the University College London – Diabetes Self-Management Programme (UCL-DSMP).

4.8.3 Feedback - Social Support Intervention

Participants in the social support intervention were again enthusiastic, however as with the standard intervention a number of issues were noted by the facilitators. Firstly, it was felt that there was less commitment to the sessions by partners rather than participants. One partner only attended one session whilst another couple only attended together on three of the five sessions. In addition, one couple commented that having been married for 40 years they did not feel it appropriate to start changing the way they related to each other. The facilitators also commented that the sessions appeared more useful for the younger rather than older couples.

4.8.4 Final Version of the Social Support Intervention and Manual

Although informative the comments made by the facilitators did not directly impact on the manual or intervention content, rather they addressed issues of whom should be targeted for such an intervention. The only changes made therefore corresponded to those made in the standard manual and intervention. This was to ensure the two SMIs remained as similar to each other as possible with the exception of the social support element.

4.9 Facilitator Training

The techniques used in the SMI were based on psychological theories and were unlikely to be familiar to the health care providers facilitating the intervention. It was therefore considered essential that all facilitators undertook training before implementing the intervention. To address these training needs a teaching programme was set up as described below: The thesis candidate designed the training programme. Delivery of the training programme was led by the candidate's supervisor but with assistance from the candidate.

Session 1 (1/2 day) - Theory of Self-Management. - A brief background to the theoretical basis of SMIs including SCT, SRM, TTM and problem solving theory.

Session 2 (1 day) - Facilitating Small Groups. - This session was designed specifically for facilitators working with groups of chronically ill patients, and dealt with issues such as group dynamics and how to deal with 'difficult' participants.

*Session 3 (2 * 1/2 day) - Brainstorming and Goal Setting Skills.* - These sessions discussed the techniques that would be used to facilitate behaviour change and included exercises where trainees had an opportunity to practise these techniques.

Session 4 (1/2 day) - Social Support Skills. - This session focussed on communication skills and the techniques to be used for the social support intervention.

As the facilitators had not previously had experience of using the skills taught in the training programme an ongoing programme of supervision was set-up. This occurred at the end of each session by discussion with the thesis candidate. This ran throughout the interventions evaluation with the aim of ensuring appropriate behaviour change skills were used and slip backs to didactic teaching did not occur.

CHAPTER FIVE: TRIAL DESIGN, MEASUREMENT TOOLS AND EVALUATION

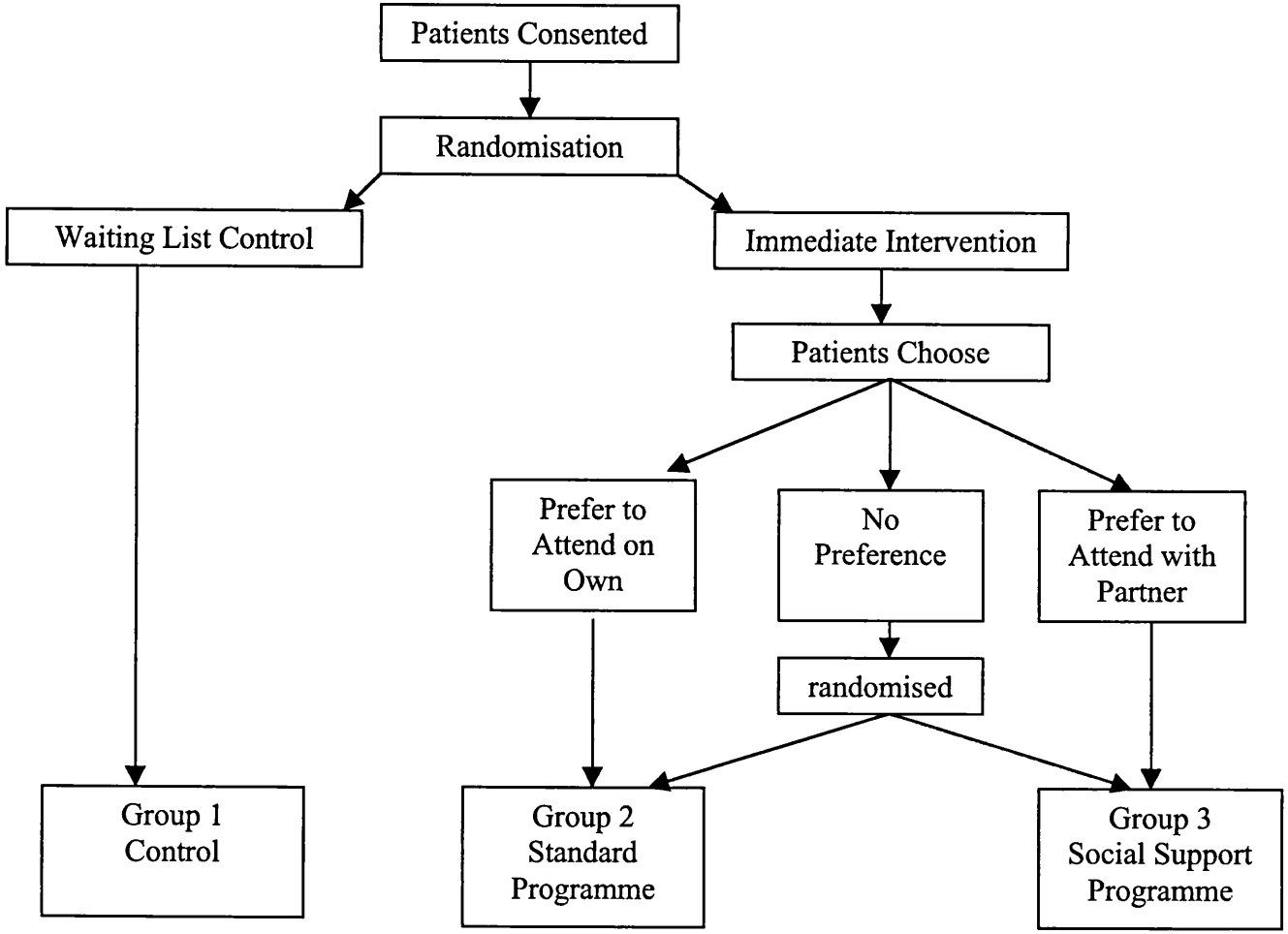
5.1 Structure of the Chapter

The current chapter describes the methods used for evaluation of the two SMIs. The chapter begins with a description of the trial design, followed by inclusion/exclusion criteria for participants, methods of consent and randomisation, and the assessment procedure. Descriptions of all measures and why each specific measure was selected for use in the current study are given, together with psychometric data of the questionnaires. The chapter concludes with an overview of the statistical analysis used to evaluate the study.

5.2 Trial Design

The trial was designed to compare three groups i) a standard SMI, ii) a social support SMI, iii) a standard treatment control group. A part randomised, patient preference design (see figure 5.1) was selected. In this design individuals were initially randomised to immediate intervention or standard treatment control group. The standard treatment control group were told they would be offered to attend either SMI upon study completion. Individuals allocated to immediate intervention had the choice of whether to attend the intervention with a partner or alone. A partner was defined as any individual with whom the patient had close and regular contact, therefore a child (providing > 18 years of age) or friend could have been considered a partner as well as a spouse. It was made clear that if participants selected to attend the intervention with a partner they would both be expected to attend all of the sessions. If participants had no preference as to whether they attended alone or with a partner they were randomly allocated between these two groups.

Figure 5.1: Trial Design – A Part Randomised, Patient Preference Trial



A part randomised preference trial was selected because it was felt unrealistic to expect all participants to have the option of bringing a partner to sessions. For some people, especially in the older age range there may not have been any individual with whom they maintained close contact. Alternatively although a partner may have been present it may have been impractical for them to give the time commitment, or there may have been a lack of desire for them to attend the SMI either by the patient or by the partner themselves. Direct randomisation between the three groups was therefore felt to be inappropriate.

5.3 Ethical Approval

Ethical approval was sought and obtained for all stages of the research project including the development phase, which involved focus groups, interviews and piloting, and for the full trial. The Whittington Hospital Local Research Ethics Committee and the University College London Hospitals (UCLH) Research Ethics Committee gave approval.

5.4 Participants

Participants were recruited from two hospital based diabetes outpatient clinics in London. These were the Whittington Hospital and the Middlesex Hospital. For individuals to be eligible for the study all of the following criteria were required:

i) The individual had a diagnosis of type 2 diabetes as recorded in the patient's notes.

ii) The individual had a diagnosis of diabetes related microalbuminuria or proteinuria defined as

- Two or more albumin creatinine ratio's >3.0 mg/mmol, or
- 24hr urinary albumin excretion rate >30mg/24hr

iii) The individual could speak fluent English

iv) The individual was willing to commit to attending all sessions of the SMI

Individuals were excluded from the study if:

i) The individual was diagnosed with advanced renal disease, defined as

- A protein excretion rate of >3.0g/24hr or >0.2g/mmol
- A creatinine level of >170μmol/l

ii) A diagnosis of functional psychosis or organic brain disorder was present

iii) The individual was unable to comprehend or complete baseline assessments

iv) An evaluation of HbA1c was unable to be obtained

5.5 Consent and Randomisation

The thesis candidate screened all clinic patients' notes for eligibility. Individuals identified as potentially fitting the inclusion/exclusion criteria were highlighted to the doctor by placing a sheet on the front of the notes. The doctor confirmed eligibility of those patients who had been highlighted during the medical consultation. If the inclusion/exclusion criteria were fulfilled they then briefly described the study and endorsed the benefits of a SMI to the patient. This was done according to a recruitment schedule (see appendix one). If the patient expressed an interest in the study they were referred to the thesis candidate who then explained the study in more detail, including the randomisation and assessment procedure.

The thesis candidate explained to the patient that the study was looking at the benefits of two types of self-management intervention and these were being compared to normal treatment. The two self-management interventions were described including the length of time of sessions, the topics that would be included and the fact that one required attendance alone and the other required attendance with a partner. It was explained that whether they attended alone or with a partner was the individual's decision,

although it was emphasised that the partner would need to attend all sessions in the social support intervention. The concept of randomisation between normal treatment and intervention was presented and the likelihood of randomisation to each group explained. When there were three arms to the trial it was explained that there would be a 1 in 3 chance of being randomised to the normal treatment group and 2 in 3 chance of being randomised to intervention. When the social support arm of the trial was closed randomisation was explained as a 50:50 chance of being randomised to normal treatment or intervention. It was stated that anyone randomised to normal treatment would be offered the opportunity of attending either of the two self-management interventions once all follow-up assessments had been conducted (i.e. after nine months). All individuals were given a written information sheet (see appendix one) and offered an opportunity to think about whether they would like to take part in the study before they consented to the study.

Participants who consented to take part in the study completed a consent form (see appendix one) and were then randomised to either immediate intervention or standard treatment control group. The immediate intervention group were then asked their preference for attending the intervention alone or with a partner.

Randomisation was by alternate allocation to immediate intervention or standard treatment control group. This was initially at a ratio of 2:1 (intervention: control) because of the two immediate intervention arms to one control arm, however when it became necessary to close the social support arm of the trial randomisation was at a ratio of 1:1. Although this method of randomisation does not adhere to allocation concealment it was necessary as the time period for recruitment was limited, and it was important to ensure sufficient participants took part in any one self-management group. To avoid bias

consent forms were ordered and marked with control or intervention. The thesis candidate was not aware of which group an individual would be randomised to when explaining the trial to a patient, as individuals were permitted to take time to consider the study before consenting and subsequently being randomised. During this period between an individual discussing the study and consenting to participate an unknown number of other participants could have been consented and randomised, hence influencing the group to which the patient would be allocated.

5.6 Assessment Procedure

5.6.1 Immediate Intervention

Following recruitment immediate intervention participants were invited to the next available programme, taking account of their preference for attending the intervention alone or with a partner. Baseline assessments for this group were completed in the two weeks prior to session one of the intervention they were allocated to. At this visit participants completed a number of questionnaire assessments (see appendix two for study questionnaires), had their blood pressure taken, and had a blood test measuring HbA1c if this had not been completed within the previous 4 weeks. In the two weeks following session five of the intervention, immediate post-intervention (IPI), assessments were completed which consisted of questionnaire assessments and blood pressure measurement. Three months after the completion of the programme one booster session was held. Three month follow-up assessments (3mths) took place in the two weeks following the booster session. Nine month follow-up assessments (9mths) then followed at 9 months post-intervention (±2 weeks). At both 3 and 9 months follow-ups questionnaires and blood pressure were recorded, and blood tests for HbA1c were taken, unless they had been done within the previous 4 weeks.

In most cases assessments were conducted within the diabetes outpatient clinic at a time agreed with the participant. In some instances, however, where it was not possible for the participant to attend the hospital, the individual was either visited at home, or if this was not possible, the individual completed the assessments alone and posted them to the thesis candidate. Efforts were made to ensure consistency in the method used for any one individual.

5.6.2 Standard Treatment Control

An appointment was made for baseline assessment within two weeks of recruitment. Follow-up assessments for this group were completed 6-8 weeks later (corresponding to IPI in the intervention groups). Three months (±2 weeks) and 9 months (±2 weeks) later further assessments were completed (corresponding to 3mths and 9 mths follow-ups in the intervention group. As with the intervention group assessments were ideally conducted in the outpatient clinic but could be conducted at the participant's home or by postal reply if these were the only options.

5.7 Measurement Tools

5.7.1 Assessment of Demographic Variables

Details of a participant's age, ethnicity, marital status, current work status, age of leaving school, highest educational qualification and duration of diabetes were recorded in a patient summary questionnaire at baseline.

5.7.2 Assessment of Clinical Data

5.7.2.1 Co-Morbidity Rating Assessment Procedure. - This was a basic measure of diabetes specific and non-specific co-morbidity. Participants were asked to indicate

whether they had any of eleven conditions including diabetes complications, and if so to rate the amount this affected their lives on a 4 point likert scale ranging from not at all to a great deal. For analysis only the number of diabetes complications was used. This was calculated by summation of the number of diabetes complications indicated as present. Cross-reference of the complications indicated by the participant with the medical notes was conducted. Where a discrepancy was present between the individual and the medical notes the medical notes were taken as the primary source.

Assessment Points: IPI, 9mths

5.7.2.2.Glycosylated Haemoglobin (HbA1c) - In both hospital clinics HbA1c was measured to assess long-term glycaemic control. This routinely reflects blood glucose concentrations for the preceding 120 days, but is weighted such that blood glucose levels over the 1 month before testing contributes approximately 50% of the value (Pickup, 1997). The method of measurement was high performance liquid chromatography with a reference range of 4.0- 6.0mmol. Values were adjusted to ensure DCCT alignment.

Assessment points: Baseline, 3mths, 9mths

5.7.2.3. Blood Pressure - Systolic and diastolic blood pressures were measured using the Omron HEM-705CP. This is an automated blood pressure measuring device that has been validated (O'Brien, Beevers & Lip, 2001) and is recommended for use by the European Society of Hypertension (O'Brien, Waeber, Parati, Staessen & Myers, 2001). Measurement of blood pressure was performed following completion of questionnaire assessments. This ensured that participants had been at rest for > 5 minutes before measurement. Two seated measurements were taken, with 2 minutes rest between

each and the second reading recorded. Measurements were always made on the non-dominant arm, which was supported and where appropriate a large cuff was used.

Assessment Points: Baseline, IPI, 3mths, 9mths

5.7.3 Assessment of Behaviour

A common objective of SMIs is to improve self-management behaviours. It is important therefore to evaluate the frequency of such behaviours before and after the intervention. Measurement of behaviours is distinct to measurement of adherence, the latter implying assessment of behaviours in relation to prescriptions from a health care professional.

5.7.3.1 Selection of Measure of Behaviour - Assessment of diabetes self-management behaviours can be by objective assessment e.g. lipids levels, pedometer readouts, blood glucose monitor memories, etc. or by self-report measurement. Although objective assessment of behaviour may be ideal, self-report data is often more practical and has shown association with objective outcomes (Heisler, Smith, Hayward, Krein & Kerr, 2003). Self-report assessment was therefore selected in the current study.

A number of self-report measures particularly for diet and exercise have been developed and used in studies with individuals with diabetes. Food frequency questionnaires and diaries have often been used to assess dietary behaviour. These however tend to be quite lengthy and time-consuming. A briefer measure of dietary behaviour has been developed by Kristal *et al.,* (1990), however this only focuses on low-fat dietary behaviours and does not consider other aspects of diet that may be important in diabetes. For exercise assessment it is important that frequency of low intensity activity as well as high impact activities are measured, especially when evaluating older populations. The Physical Activity Scale for the Elderly (PASE) (Washburn, Smith, Jette

& Janney, 1993) was designed with this in mind, however use of this measure is limited by the requirement of a fee. The revised Summary of Diabetes Self Care Activities Scale (Toobert, Hampson & Glasgow, 2000) was therefore selected as this is a brief measure, does not require payment, and covers a range of self-management behaviours.

5.7.3.2 Revised Summary of Diabetes Self-Care Activities Scale (revised SDSCA scale) (Toobert et al., 2000) - The revised SDSCA scale is a self-report questionnaire that assesses level of care in five areas of diabetes self-management, namely diet, exercise, blood glucose monitoring, foot care and smoking status. In the initial SDSCA scale a medication sub-scale was also included but this was excluded in the revised version due to high ceiling effects (Toobert *et al.,* 2000). With the exception of smoking, which is rated as number of cigarettes smoked per day, participants are asked how frequently they performed a given behaviour in the last seven days. Scoring of the questionnaire is separate for each self-care activity and is the mean of items referring to that activity. For each behaviour a score ranging between 0 to 7 can be achieved, with higher scores reflecting a better level of self-care. No overall score for self-care is provided because it has been established that correlations between different self-care behaviours are not high, and that behaviours should therefore be treated independently (Ary *et al.,* 1986; Glasgow *et al.,* 1989).

Reliability and Validity: Data on the reliability and validity of the SDSCA scale had only been published (Toobert *et al.,* 2000) for the original rather than revised scale when measure selection was required. However, given that items were retained in the revised version based on i) consistency in mean values across studies, ii) sufficient variability and lack of ceiling or floor effects, iii) temporal stability, iv) internal consistency, v) predictive validity, vi) sensitivity to change, vii) ease of scoring and viii) ease of interpretation (Toobert *et al.,* 2000), it was reasonable to expect that psychometric

properties would be acceptable in the revised scale. Inter-item correlations for all scales were acceptable except for specific diet, which was found to be unacceptable (r= 0.07 - 0.23) in a number of studies. Test-retest reliabilities had been reported as moderate and acceptable. Concurrent validity was demonstrated by significant correlations between scores on the SDSCA scales and related measures of self-care behaviours e.g. Kristal Food Habits Questionnaire (Kristal *et al.,* 1990), Physical Activity Scale for the Elderly, (Washburn *et al.,* 1993) etc. Sensitivity to change was also demonstrated for general diet and specific diet although findings for exercise and SMBG are less clear (Toobert *et al.,* 2000).

Limitations: As discussed above it is preferable to use objective measures of behaviour and the revised SDSCA scale relies only on self-reported behaviour. The revised scale also includes a limited number of items with only a couple of items measuring each behaviour. Although this has the strength of decreasing measure length it can potentially decrease psychometric properties and sensitivity to change. Psychometric data on the revised SDSCA scale had also not been published at the time of measure selection, although the psychometric reports for the original SDSCA scale were promising (Toobert *et al.* 2000).

Assessment Points: Baseline, IPI, 3mths, 9mths

5.7.4 Assessment of Quality of Life

QoL can be measured by generic or disease specific measures. In diabetes a number of specific measures have been developed, it has been argued that these may be more relevant to people with diabetes and do not risk leaving out important domains such as diet (Bradley, Todd, Gorton, Symonds & Plowright, 1999). Conversely, generic measures allow comparison to other illness groups or the general population. Studies comparing generic and diabetes specific QoL measures have suggested that there may

be benefit in including both forms of measure. Not only would this address the above points, but a study by Jacobsen, De Groot & Samson, (1994) indicated that a generic measure was shown to be more sensitive to change in physical aspects of diabetes while a specific measure was more sensitive to lifestyle domains. Two QoL measures were therefore selected for inclusion in the current study.

5.7.4.1 Selection of Measure of Diabetes Specific Quality of Life - A number of diabetes specific measures have been developed in the past decade including the Diabetes Quality of Life Measure DQOL (DCCT Research Group, 1988). This measure was originally designed for use with insulin dependent patients in the Diabetes Control and Complications Trial (DCCT Research Group, 1988). Although it has subsequently been used with type 2 populations, it appears that not all items are well suited to non insulin treated patients. In addition, there has been some question over the sensitivity to change following SMIs (Steed *et al.,* 2003). Other measures which may be more applicable to patients with type 2 diabetes include the Diabetes-39 (Boyer & Earp, 1997); The Diabetes Care Profile (Fitzgerald, Davis, Connell, Hess, Funnell *et al.,* 1996) or the ADDQoL (Bradley *et al.,* 1999). The ADDQoL has the advantage to these others in that it is both brief and has been validated in a UK population. In addition, it takes into account the relevance of aspects of quality of life for each individual, and has recently been recommended (Garratt, Schmidt & Fitzpatrick, 2002). The ADDQoL was therefore selected as the most appropriate diabetes specific measure to include in the present study.

5.7.4.2 Audit of Diabetes Dependent Quality of Life (ADDQoL) (Bradley, et al., 1999) - The ADDQoL includes fifteen items, thirteen of which form a composite score. The first two items are single items providing an overview of general QoL and diabetes specific

QoL respectively. The following thirteen items consider different areas of life that could be affected by diabetes, although four of these items have the option of being marked as 'not applicable'. For those items that are applicable two ratings are required i) impact, ii) importance. Impact is assessed on a 7 point likert scale with responses ranging from 'very much better' to 'very much worse', therefore recognising that diabetes may have a positive as well as negative impact on QoL. Having rated impact for each domain participants are then asked to rate how important this area of life is to them on a 4 point scale ranging from 'not at all important' through to 'very important'. Weighted scores for each of the thirteen items are calculated by multiplying the impact of a domain (-3 to +3) by its importance (0 to 3), hence a range of –9 to 9 is achievable for any one item. An overall ADDQoL score can be calculated by summing the weighted scores of all applicable domains, and then dividing by the number of applicable domains. Any domain rated as not applicable is not scored.

Reliability and Validity: Psychometric data has been evaluated from two UK samples including participants with both insulin dependent and non-insulin dependent diabetes (Bradley, 1999). A forced one factor analysis has been reported suggesting that all 13 items could be combined into an overall ADDQoL score. Cronbach's alpha for this scale is satisfactory at 0.84. Construct validity is demonstrated by the differences in scores between insulin and tablet or diet treated individuals. As hypothesised, those treated with insulin reported a more negative impact of diabetes on their QoL than tablet or diet treated patients. Furthermore, significant positive correlations in these samples between negative impact and number of complications have been shown. This is as would be expected. Sensitivity to change data was not available at the point of measure selection for the current study, however other diabetes specific QoL measures have been shown to be more sensitive to change in lifestyle domains than generic measures (Jacobsen *et al.,* 1994).

Limitations: The ADDQoL has been recommended as a useful measure of diabetes specific QoL, however the lack of data on test-retest reliability and examination of responsiveness of this measure have been highlighted (Garratt *et al.,* 2002). In addition although rating both impact and importance of different domains of QoL gives a fuller understanding of QoL it does add to the complexity of the measure.

Assessment Points: Baseline, IPI, 3mths, 9mths

5.7.4.3 Selection of Measure of Generic Quality of Life - Several generic QoL questionnaires have been developed, with possibly the most well known in the UK including the Sickness Impact Profile (SIP) (Pollard, Bobbitt, Bergner, *et al.,* 1976), the Nottingham Health Profile (NHP) (Hunt, McEwan, & McKenna, 1985), the Dartmouth Coop Charts (Nelson, Wasson, Kirk *et al.,* 1987) and the Short Form-36 (Ware & Sherboune, 1992). Each of these measures has been used frequently and demonstrated acceptable reliability and validity. Disadvantages of individual measures however include length of time for administration (SIP), a highly skewed distribution in favour of severely ill patients (NHP) and limited use with UK populations (COOP). Whilst most questionnaires will have advantages and disadvantages the SF-36 aims to overcome some of the above difficulties. It is a brief measure that was adapted from a longer scale used in the Medical Outcomes Study (Stewart & Ware, 1992). A UK version of the questionnaire has been produced and validated which has been used extensively with both healthy and non-healthy patients, including use with patients who have type 2 diabetes (Jacobsen *et al.,* 1994; Ahroni & Boyko, 2000). Population norms including variations by age have also been published for this version of the questionnaire, (Jenkinson, Layte, Wright & Coulter, 1996) and therefore it was selected as the most appropriate measure of generic QoL for use within the current study.

5.7.4.4 - United Kingdom Short Form 36 (Jenkinson et al., 1996) - The Short Form-36 (SF-36) is a thirty six item questionnaire designed for either self-completion or interviewer administration, taking approximately 5-10 minutes to complete. Eight sub-scales assess the patient's physical functioning, role limitation due to physical problems, role limitation due to emotional problems, social functioning, mental health, energy/vitality, pain, general health perception and a single item assesses change in health over the past year. The eight sub-scales can also be combined to produce two summary scales for physical and mental health. Scoring of the SF-36 involves combination and adjustment of appropriate items to give scores with a range of 0-100 for each sub-scale, with higher scores reflecting better QoL. Scores can be transformed to give a norm-based score with a mean of 50 and a standard deviation of 10, hence allowing comparison to other samples.

Reliability and Validity: For the UK version of the SF-36 criterion validity has been demonstrated by comparison to the general health perception item in the Oxford Healthy Life Survey (Wright, Harwood & Coulter, 1992), and has been found to be acceptable (Jenkinson, Layte & Lawrence, 1997). Construct validity has been demonstrated in general population groups (Brazier, Harper, Jones, O'Cathian, Thomas *et al.,* 1992) and in populations with type 2 diabetes (Jacobsen *et al.,* 1994) as demonstrated by an association between lower quality of life scores and higher number of complications (Jacobsen *et al.,* 1994; Ahroni & Boyko, 2000). The SF-36 has also shown sensitivity to change when used in diabetes (Ahroni & Boyko, 2000). Alpha coefficients range from 0.73 (social functioning) to 0.96 (role limitation, physical and emotional functioning and vitality) in a UK population (Jenkinson *et al.,* 1996). In patients with type 2 diabetes similar values have been reported ranging from 0.78-0.91, hence indicating good reliability of sub-scales.

Limitations: Although a frequently used measure the SF-36 has been open to some criticism. Specifically it has been noted that scores on the SF-36 are significantly affected by non-diabetic co-morbidity (Woodcock *et al.,* 2001). This potentially limits the sensitivity of this measure to change in interventions for individuals with type 2 diabetes. The SF-36 has also been considered more of a measure of functional status and general health than general quality of life (Woodcock *et al.,* 2001). This is one of the reasons it was considered important that both the SF-36 and ADDQoL were included in the current study.

Assessment Points: Baseline, IPI, 3mths, 9mths

5.7.5 Assessment of Psychological Well-being

In the current study measures of depression, anxiety, positive affect and negative affect were used to reflect psychological well-being. It is relatively common for studies of SMIs to measure depression and anxiety, however measurement of positive mood is often ignored. Effects of SMIs on positive mood could therefore be missed. It is important that positive affect should not be seen as just the absence of depression.

5.7.5.1 Selection of Measures of Psychological Well-being - A number of measures with acceptable psychometric properties have been developed to assess depression (Beck Depression Inventory, Beck, Ward, Mendelson, Mock & Erbaugh, (1964); Centre for Epidemiologic Studies Depression, Radloff, (1977) and anxiety, State-Trait Anxiety Inventory, (Spielberger, Gorsuch & Lushene, 1970). There has been some criticism however that inclusion of somatic items in these measures influences scoring when used with individuals with chronic illness. The Hospital Anxiety and Depression Scale (HAD Scale, Zigmond & Snaith, 1983) was developed specifically for medical out-patients and hence excludes items influenced by physical symptoms. The HAD Scale also has the

benefit of incorporating both anxiety and depression sub-scales into a brief self-completion measure. For these reasons, the HAD Scale was selected for assessment of anxiety and depression in the current study.

The short form Positive and Negative Affect Scale (PANAS) (Mackinnon, Jorm, Christensen, Korten, Jacomb *et al.,* 1999) was selected for assessment of positive and negative mood because of its brevity, and demonstrated reliability and validity. Other measures such as the Profile of Mood States (POMS) (McNair, Lorr & Droppiman, 1971) and the Well-Being Questionnaire (W-BQ) (Bradley, 1996) also assess positive and negative mood. These measures were not selected however because of limited psychometric data at the time of measure selection, (W-BQ) and length of the measure (POMS).

5.7.5.2 Hospital Anxiety and Depression Scale (HAD Scale) (Zigmond & Snaith, 1983) - The HAD Scale is a brief self-completion questionnaire, which consists of 14 items, 7 assessing depression and 7 assessing anxiety. All items are scored between 0-3 and hence both subscales can have total scores between 0-21. For both anxiety and depression higher scores indicate greater symptomatology. A cut-off of >7/8 indicates possible clinical disorder, and a cut-off of >10/11 indicates probable clinical disorder (Zigmond & Snaith, 1983), however the level of cut-off has tended to vary between studies (Herrmann, 1997).

Reliability and Validity: A review of studies using the HAD Scale was reported by Herrmann, (1997) and provides considerable data on the psychometric properties of the measure. Internal consistency for the anxiety and depression subscales has been reported to be 0.80 and 0.81 respectively. Retest reliability has been reported to be high after short intervals (r>0.80) but decreases over longer periods, indicating that the

HAD Scale should be sensitive to changes in mood. Factor analysis confirms the two sub-scales of depression and anxiety. Discriminant validity is demonstrated by a mean correlation between the two scales of 0.63, but partial correlations demonstrate that each sub-scale is independent. Concurrent validity has been assessed by comparing HAD Scale scores and 5 point psychiatric rating scales in medical outpatients. Validity has also been demonstrated by the finding that patients with moderate-severe symptoms are more likely to ask for psychological help. Higher scores on the HAD Scale have also been shown to be associated with poorer glycaemic control in men (Lloyd, Dyer & Barnett, 2000).

Limitations: There are relatively few limitations to the HAD scale given it is brief, was developed specifically for medical outpatients, and has extensive data on reliability and validity (Herrmann, 1997). One criticism is that it does not discriminate well between individuals with major depressive disorder and those with depression occurring as a symptom of other psychiatric disorders (Hermann, 1997), however as this was not an objective of the current study this was not viewed as a reason to exclude the measure.

Assessment Points: Baseline, IPI, 3mths, 9mths

5.7.5.3 Short Form Positive and Negative Affect Schedule (PANAS) (Mackinnon et al., 1999) - The short form PANAS is a shortened version of the original PANAS (Watson, Clark & Tellegran, 1988). It is a 10 item questionnaire comprising five adjectives representing negative affect and five adjectives representing positive affect. Each item is rated on a 1-5 scale where one represents 'very slightly or not experienced at all' and five represents 'extreme' amounts of this feeling. Scoring for the two separate sub-scales is by summation of adjectives hence a range of scores from 5-25 for each scale is possible.

Reliability and Validity: Psychometric data on the short form PANAS has been reported by Mackinnon *et al.,* 1999. Confirmatory factor analysis indicates that a two factor model of positive and negative affect fits the data (Mackinnon *et al.,* 1999). Cronbach's alphas of 0.78 and 0.87 have been reported for positive and negative affect respectively and indicate acceptable internal reliability. Correlation analyses between scales, although statistically significant, are reportedly small and acceptable. Construct validity for the measure has also been reported through the scales ability to differentiate robustly on gender and financial hardship, with higher negative affect associated with being female and increased financial hardship (Mackinnon *et al.,* 1999).

Limitations: Although the PANAS incorporates a measure of positive affect it has not been used frequently in the type 2 diabetes population. In addition the measure's sensitivity to change following a SMI is unclear.

Assessment Points: Baseline, IPI, 3mths, 9mths

5.7.6 Assessment of Process Variables

To understand the process through which SMIs act it is important to evaluate change on process variables. The process variables included in the current study were those which would be predicted to change based on the theories from which the intervention was drawn, i.e. SCT, SRM, TTM and social support. Knowledge was included along with these process measures to allow comparability to evaluations of other SMIs, which frequently measure knowledge.

5.7.6.1 Selection of Measure of Knowledge - Numerous measures of diabetes knowledge are available, for example the ADKnowl (Speight & Bradley, 1999) the Patient Knowledge Test (Garrard, Ostom Joynes & Mullen, 1987) and the DKN scales (Dunn, Bryson, Hoskins, Alford, Handelsman *et al.,* 1984). The first two of these

measures may be particularly useful for identifying knowledge deficits, however are rather lengthy for evaluation of SMIs. The DKN scales (Dunn *et al.,* 1984), which were designed specifically for evaluation of education programmes, are briefer and come in different versions for repeated application. Some of the items on the DKN scales however are dated, for example references are made to food substitutions that are no longer part of routine clinical practice within the UK. The Michigan Diabetes Research and Training Centre Brief Knowledge Test (Fitzgerald, Funnell, Hess, Barr, Anderson, *et al.,* 1998) which has been developed more recently and has good psychometric properties was therefore felt to be more appropriate for inclusion in the current study.

5.7.6.2 Michigan Diabetes Research and Training Centre (MDRTC) Brief Diabetes Knowledge Test (Fitzgerald et al., 1998) - The MDRTC Brief Diabetes Knowledge Test is a 23 item multiple choice, knowledge test. Fourteen items test general diabetes knowledge and a further nine items assess knowledge about insulin use. In the current study only the general diabetes questions were included. This was because not all participants in the current study used insulin. Scoring of the questionnaire was based on percentage of correct answers, with one correct answer per question. A correct answer was scored as 1 and incorrect or blank answers were scored as 0, higher percentages therefore indicate greater knowledge. Two minor changes were made to the original questionnaire for the current study. Firstly in item 1 the option a) 'the way most American people eat' was changed to a)'the way most British people eat'. In item 8 the option a) 3 hard candies was changed to a) 3 hard sweets. These minor changes were to reflect differences in language between America and Britain and would not be expected to affect psychometric properties.

Reliability and Validity: Reliability has been demonstrated in two separate samples for both the general and insulin use sub-scales (Cronbach's alpha > 0.71). Validity has also

also been indicated by the achievement of higher scores by individuals with higher educational level, type 1 versus type 2 diabetes, and attendance at a diabetes education programme.

Limitations: The MDRTC Brief Diabetes Knowledge Test by definition is brief and has demonstrated reliability and validity, however it is subject to a number of criticisms. There is an emphasis on dietary knowledge, with seven of the fourteen general items focusing on diet, while only three items are dedicated to other aspects of the self-management regimen. The brevity of the measure also means it cannot be used to assess the specific knowledge acquired within a SMI. However as this was not the primary objective of the current study this was not considered a reason to discount it.

Assessment Points: Baseline, IPI, 3mths

5.7.6.3 Selection of Measure of Self-Efficacy - Diabetes specific self-efficacy scales have been developed for use with adult type 2 patients and include those by Anderson, Funnell, Fitzgerald & Marrero, (2000), Talbot, Nouwen, Gingras, Gosselin & Audet, (1997), and Kingery & Glasgow, (1989). The Diabetes Empowerment Scale as developed by Anderson *et al.,* (2000) is a measure of psychosocial self-efficacy and was designed specifically for evaluation of SMIs. This scale was not included in the current study however, as it was still at a development stage when the current trial was commencing, and psychometric data on the scale was not clear. The scales by Talbot *et al.,* (1997) and Kingery & Glasgow, (1989) both assess self-efficacy to specific behaviours in the diabetes regimen, however the Talbot *et al.,* (1997) self-efficacy scale, has the benefit of using only 7 items versus the 29 items included in the Kingery & Glasgow, (1989) measure. In addition, the Talbot *et al.,* (1997) measure assesses self-efficacy for overall ability to follow diabetes treatment in addition to diet, exercise and blood glucose monitoring, which was felt to be desirable for the current study.

5.7.6.4 Multidimensional Diabetes Questionnaire – Self-Efficacy Sub-Scale (Talbot et al., 1997) - This self-efficacy scale is a sub-scale taken from the Multidimensional Diabetes Questionnaire and includes 7 items. The 7 items relate to different aspects of the diabetes regimen including diet, exercise, blood glucose monitoring, weight control, blood glucose control and overall diabetes treatment. For each item the participant is required to indicate their confidence in performing the behaviour on a scale of 0-100 where 0 reflects not at all confident and 100 reflects very confident. For the exercise and blood glucose scales participants can indicate if the item is not applicable to them. Items can be combined into a single self-efficacy index by summing all relevant items and dividing by the number of relevant items, alternatively self-efficacy for individual behaviours can be examined.

Reliability and Validity: The reliability coefficient for the self-efficacy sub-scale of this measure is 0.89. Construct validity has been demonstrated by significant positive correlations between self-efficacy and diet and exercise behaviour, and significant negative correlations between self-efficacy and depression and HbA1c. This follows the pattern that would be expected and hence suggests the measure is valid.

Limitations: At the time of measure selection the self-efficacy scale of the MDQ was limited by sparse data on sensitivity to change following SMIs in type 2 diabetes. In addition the composite score had been used more frequently than individual items. However, given the design and measurement scale of the items was as suggested by Bandura, (1997) the scale was felt to be appropriate.

Assessment Points: Baseline, IPI, 3mths, 9mths

5.7.6.5 Selection of Measure of Illness Cognitions - For type 2 diabetes two validated measures of diabetes specific beliefs have been developed, the Health Belief Scales

(Lewis, Jennings, Ward & Bradley, 1990) and the Beliefs about Diabetes Scale (Hampson *et al.,* 1995, 2000). The Health Belief Scale assesses perceived benefits of, and barriers to treatment, and perceived severity of and vulnerability to complications. This measure is based upon the Health Belief Model (Becker, 1974) and constructs are researcher generated. In contrast, the Beliefs about Diabetes Scale is based upon Leventhal's SRM (Leventhal *et al.,* 1984) with the components of personal models being empirically derived from studies with patients (Hampson *et al.,* 1990, 1995). The Beliefs about Diabetes Scale was selected for use in the current study because the SRM, upon which it is based, was used to guide development of the SMI evaluated in the current study.

5.7.6.6 Beliefs about Diabetes Scale (Hampson et al., 1995, 2000) - This measure of illness beliefs includes eleven items split into the three sub-scales of seriousness (3 items), treatment effectiveness (6 items) and control (2 items). Each item is rated on a 5 point likert scale ranging from 'Not at all' to 'Extremely'. Scoring is calculated as the mean of each scale and scores can range from 1-5 with higher scores reflecting greater endorsement of the belief. An extended version of this scale is also available with additional items asking about the importance of aspects of the diabetes regimen for controlling diabetes, and the likelihood of these behaviours in preventing future complications. The additional items were not included in the current study however because of participant burden.

Reliability and Validity: Reliability coefficients for the three scales of the Personal Models measure have been reported as moderate and acceptable, although the control scale is the weakest of the three (Seriousness, α=.57, Treatment Effectiveness, α=.74, Control, α=.53). Inter-item correlations are in the directions expected (seriousness and control r=-.38, p<0.001, seriousness and treatment effectiveness r=.29, p<0.001, treatment

effectiveness and control r=.17, p<0.05). The validity of this measure has also been indicated by the prediction of concurrent and future self-management behaviours (Glasgow *et al.,* 1997; Hampson *et al.,* 2000).

Limitations: Although this measure had demonstrated prediction of concurrent and future self-management behaviours at the time of selection, data on sensitivity to change following interventions was not known. This is a common finding for measures however, as this aspect of psychometric data is frequently not assessed.

Assessment Points: Baseline, IPI, 3mths, 9mths

5.7.6.7 Selection of Measure of Readiness to Change (RTC) - A number of questionnaires have been developed that aim to measure the stages or 'readiness' of change to a behaviour as proposed in Prochaska and DiClemente's, (1984) TTM. These include the University of Rhode Island Change Assessment Questionnaire (URICA; McConnaughy, Prochaska & Velicer, 1983), and the Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES, Miller & Tonigan,1996). The measures have been used in a number of areas including diabetes (Trigwell, Grant & House, 1997). One difficulty with the use of these measures is that they do not independently assess stages of change for the different behaviours in diabetes self-management, rather a more global perspective is taken e.g. 'looking after diabetes'. It was considered inappropriate to combine the different self-management behaviours in this way, given the low correlation between different self-management behaviours. To include a separate stages of change measure for each diabetes self-management behaviour however was considered impractical due to the length of these previously developed measures. A brief questionnaire was therefore designed for the current study with separate items for diet, exercise, SMBG and medication or insulin use.

5.7.6.8 Diabetes Specific Readiness to Change Scale (developed for study) - A four item questionnaire assessing individuals RTC diet, exercise, SMBG and medication or insulin use behaviour was developed for the current study. Each item asked to what extent the participant would agree to make changes to a given behaviour if advised to do so by the diabetes team. Responses were on a seven point likert scale ranging from strongly disagree to strongly agree. Each item was rated from 1 to 7 with higher scores reflecting greater RTC. It was not intended that items would be combined, as distinction between behaviours was expected.

Reliability and Validity: As the questionnaire was developed for this study there was no prior reliability or validity data.

Limitations: It is generally preferable to use previously developed and validated measures of a construct, however because of the reasons given above this was not felt appropriate for measurement of RTC in the current study. Specific limitations of the scale were therefore unknown until data from the current study was acquired.

Assessment Points: Baseline, IPI, 3mths, 9mths

5.7.6.9 Selection of Measure of Diabetes Specific Social Support - The Diabetes Family Behavior Scale (DFSB), and the Diabetes Family Behavior Checklist (Schafer, McCaul, Glasgow, 1986) have both been developed to assess family supportive and non-supportive behaviours in type 1 diabetes. The Diabetes Family Behavior Checklist II (Glasgow & Toobert, 1988) has also been modified for use with type 2 diabetes. The DFBC II provides scales on both positive and negative supportive behaviours and can be scored to provide scales for the different areas of the diabetes regimen. Due to these features it was felt to be the most suitable diabetes specific measure of social support for the current study.

5.7.6.10 - Diabetes Family Behavior Checklist II (DFBC II) (Glasgow & Toobert, 1988) - The DFBC II assesses how frequently both supportive and non-supportive behaviours are carried out by an individual nominated by the patient. It includes 17 items 9 of which assess supportive behaviours, 7 of which assess non-supportive behaviours, plus one open-ended item. Each item is rated on a 5 point likert scale ranging from 'never' to 'at least once a day'. Scoring can be calculated independently for diet, exercise, SMBG and medication by subtracting the mean of the non-supportive items for a regimen area from the supportive items for the area. In addition composite scales of positive and negative supportive behaviours can be calculated by simply taking the means of all supportive items and means of all non-supportive items respectively. This scale can be extended by including items that assess the perceived helpfulness of each behaviour. The extended scale was not used in the current study as the perceived helpfulness ratings have not been shown to consistently improve predictability of behaviour (personal correspondence).

Reliability and Validity: Internal consistency for the positive and negative sub-scales have been shown to be acceptable (α = 0.71 and α = 0.61 respectively), however they are poor for the separate regimen areas (mean α = 0.34), which could be explained by the small number of items per scale (Glasgow *et al.,* 1988). The test retest correlation for overall support has been reported as r= .55, however less stability has been reported for individual regimen areas (diet r= .59, exercise r=.76, glucose testing r=.22, medication r= .05). Predictive validity has been demonstrated in relation to adherence and was best when supportive behaviours were assessed for independent regimen areas.

Limitations: Although the DFBC II was selected as the most appropriate diabetes specific social support scale there are some concerns related to this measure. These include, poor psychometric data for some sub-scales, lack of sensitivity to change data and a requirement of an individual to be able to identify a support individual. This later

requirement is in common with other measures of social support but presents a problem where individuals do not have any support individual in their lives.

Assessment Points: Baseline, IPI, 3mths

5.7.6.11 Selection of Measure for Generic Social Support - Social support has been measured in two main ways. The first focuses on social network, i.e. the size or number of individuals available to provide support. The second focuses on an individual's satisfaction with the support they perceive to have available. Zimet, Dahlen, Zimet, & Farley, (1988) have reported that " most authors have found perceived social support to be a better predictor of psychological status than objectively measured social support." The purpose of including a generic social support scale in the current study was as a predictor of outcomes following the SMI. A measure of perceived support rather than social network was therefore included. Many of the available measures of perceived support are lengthy e.g. Social Support Questionnaire (Sarason, Levine, Basham & Sarason, 1983), or have not demonstrated acceptable reliability and validity. The Multidimensional Scale of Perceived Social Support (MSPSS, Zimet *et al.,* 1988) overcomes these difficulties by being a brief measure with psychometric properties demonstrated in a range of samples. It was therefore selected for use in the current study.

5.7.6.12 The Multidimensional Scale of Perceived Social Support (MSPSS) (Zimet et al., 1988) - This twelve item measure of perceived social support is comprised of three sub-scales i) significant other, ii) family and iii) friends. Each item is rated between 1 'very strongly disagree' to 7 'very strongly agree'. Sub-scale scores are calculated as the mean of the four items. In addition, the mean of all items can be calculated to provide a total index of perceived support with higher scores reflecting greater levels of support.

Reliability and Validity: Confirmatory factor analysis has confirmed the three sub-scale groupings proposed by the authors for family, significant others and friends. Reliability coefficients have been reported to range from 0.85-0.91 for the three individual scales and 0.88 for the total scale. Construct validity has been demonstrated by studies showing significant negative correlations between all sub-scales and depression. The reliability and validity of this measure was therefore felt to be acceptable.

Limitations: Although an established measure it is important that the original psychometric data for this measure was acquired with university students. The extent that data varies for older individuals with type 2 diabetes is unclear. A second weakness of the measure is a lack of a not applicable option for people who may not have a 'significant other', 'family' or 'friends'. This has the potential to give misleading results, by not differentiating between lack of a support individual and poor support from an individual that is present.

Assessment Points: Baseline

5.8. Statistical Analysis

5.8.1 Data Cleaning

Before analysis of the dataset, data cleaning was conducted. The purpose of this was to ensure the accuracy with which data was entered into the data file and to test for basic assumptions common to many multivariate analyses. Further assumptions, specific to individual statistical analysis, were conducted as appropriate before the analysis.

5.8.1.1. Missing Data - Screening for incorrect data entry was conducted by examination of frequency reports for all variables. Erroneous values were corrected by verification with source data. Where data was missing in a random pattern (≈ 0.2% of data), values were imputed by inserting the mean value for item by group as recommended by

Tabachnick & Fiddell, (1996). Where missing data was systematic i.e. whole assessment missed, or questionnaire not completed, imputation was not performed. Variation in study 'n' due to missing data and reasons for absence of assessment are reported as appropriate in the results section. For two variables, diastolic and systolic blood pressure the amount of missing data, particularly on follow-up assessments was extensive (26% at baseline increasing to 48% at 6months). The reasons for this were i) measurements not performed due to participants completing assessments at home rather than returning to clinic, ii) error with the measurement tool. Due to the extent of missing data these variables were dropped from the analysis.

5.8.1.2 Outliers –These are problematic in statistical analysis because of the risk of a type 1 or type 2 error, that is incurred when present (Tabachnick & Fidell, 1996). Management of outliers is dependent on type of analysis and whether data is grouped or ungrouped e.g. ANCOVA versus Regression. For this reason outliers were explored separately before each analysis. In general management involved identification and exclusion of extreme scores (greater than 3 standard deviations from the mean). Typically however there were few (≤ 1) extreme scores for any variable within each analysis.

5.8.1.2 - Normality, Linearity, Homoscedasticity

All scales acceptable for analysis were subject to tests for normality using the Kolmogorov-Smirnov test, (see appendix four). Some scales were identified as non-normally distributed and hence were subjected to transformations. It was not, however possible to transform certain outcomes e.g. self-management behaviours, and in addition single transformations did not adequately normalise data at each assessment period. In addition for anxiety and depression it was not expected that normality be

present. Further, analysis of covariance and regression are said to be relatively robust to violations of normality, linearity and homoscedasticity provided outliers are excluded (Tabachnick & Fidell, 1996). Transformed scores were therefore not used in data analysis.

5.8.2 Examination of Sample Characteristics at Baseline – (See Chapters 6 & 7 for results and discussion)

Participants and non-participants were compared on basic demographic variables (see appendix four). Means and standard deviation for both intervention and control groups and total sample were then calculated for all variables. Statistical differences ($p \leq 0.05$) between intervention and control groups on categorical variables were tested for using Chi-Square analysis with Yates correction as appropriate. For continuous variables differences between groups were examined by t-test.

To explore association between baseline variables Pearson correlation coefficients were performed on continuous variables (see appendix five). A significance level of $p \leq 0.01$ was set due to the large number of associations explored and the risk for a type 1 error. The association of categorical variables to continuous variables was explored by analysis of variance.

5.8.3. Testing Efficacy of the Intervention - (See Chapters 8 & 9 for Results and Discussion)

To explore intervention efficacy analysis of covariance (ANCOVA) using baseline scores as the covariates was conducted. ANCOVA was selected as a more stringent and potentially more powerful form of comparison than repeated measures analysis of

variance (Tabachnick & Fiddell, 1996). It has also been recommended as the most appropriate form of examining efficacy in clinical trials (Hewett, Anderson & Minor, 1992). Separate analyses were performed for dependent variables at IPI, 3 month and 9 month follow-ups. This allowed the impact of the intervention at the three separate time points to be examined. Power was also increased by conducting ANCOVAs at each follow-up and hence participant numbers were maximised. As part of the ANCOVA analyses post-hoc Bonferroni adjusted t-tests were conducted to explore differences within groups from baseline to follow-up and allow for full understanding of the data. Comparisons reported as significant are only those that survived Bonferonni adjustment.

Although separate ANCOVAs at each assessment are a more powerful approach to examine intervention efficacy, maintenance of changes between follow-up assessments is difficult to ascertain from this analyses. For this purpose a series of within group, Bonferroni corrected, post-hoc tests was performed following repeated measure analysis of variance (ANOVA). Again comparisons reported as significant are only those that survived Bonferonni adjustment.

In both ANCOVA and repeated measure ANOVA analysis, participants who 'dropped out' of the programme were excluded. This was because the primary research question was of intervention efficacy, i.e. given attendance at the programme did it work? This is in contrast to a test of intervention effectiveness that asks more broadly whether an intervention offered to a specific population has benefits. To address intervention effectiveness an intention to treat model should be used. This was not the primary research question of the current thesis, and hence was not addressed, however analysis

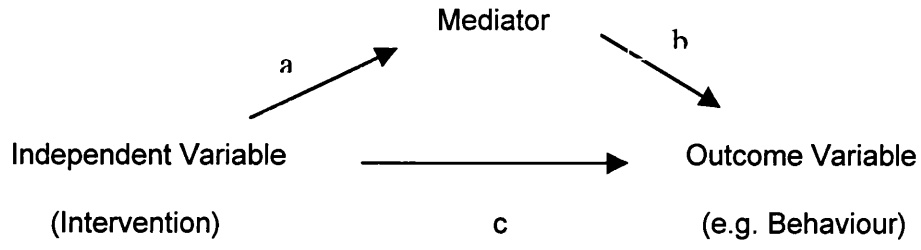
of the effectiveness of the UCL-DSMP has been published in the scientific literature (Steed et al, in press, see appendix six).

5.8.4 Mediation Analysis (See Chapters 10 & 11 for Results and Discussion)

Having demonstrated intervention efficacy the extent that variables mediated change in behaviour and QoL was explored. The variables considered as mediators were change in knowledge, self-efficacy, personal models of diabetes and RTC. Aside from knowledge the variables selected were those specified in the social cognitive theories that guided intervention development (i.e. SCT, SRM, TTM). It was hypothesised that change in outcomes would act through change in these variables, hence they would be identified as mediators. Knowledge was also tested to examine the hypothesis that this would be a weaker mediator than theoretically derived variables.

To test for mediation the methods described by Baron & Kenny (1986) and Mackinnon *et al.,* (2001) were followed. A model of mediation is shown in Figure 5.2

Figure 5.2 – Mediation of Behaviour Change



It has been stated that for a variable to be shown to mediate the intervention three conditions must be met.

i) Change in the outcome variable must be significantly predicted by the intervention (path c in figure 5.2 - tested by regressing the independent variable on the outcome variable)

ii) Change in the potential mediator must be significantly predicted by the intervention (path a in figure 5.2 - tested by regression the independent variable on the mediator)

iii) Change in the outcome variable must be significantly predicted by change in the mediator (path b in figure 5.2 - tested by regressing the mediator on the outcome variable) and must remain significant when the intervention is controlled for (tested by regressing both the independent variable and mediator on outcome variable within single equation).

If all three conditions are true the extent of mediation can be examined. Full mediation is present when the intervention coefficient in step three of the analysis is equal to zero. If there was not evidence of full mediation then the extent of mediation was calculated as the product of the program effect on the mediator (pathway a) and the mediator effect on the outcome (pathway b). The significance of this effect was calculated following the method described by Baron and Kenny, (1986).

In conducting these analyses multiple regression on residualised change scores were used. Residualised change scores were used in preference to delta scores as these adjust for baseline scores and account for the difficulty of ceiling effects, which were present for some scales (e.g. self-management behaviours). Residualised change scores have also been recommended as more reliable than delta scores (Llabre, Spitzer, Saab, Ironson & Schneiderman, 1991). Prior to regression analysis extreme

outliers were removed. Single mediator models were tested unless two mediators for an outcome were identified in which case a multiple mediator model was also tested. This allowed for examination of whether the mediation effect of a variable was accounted for by other potential mediators and has been recommended by McKinnon *et al.,* 2001.

5.8.5 Prediction of Intervention Efficacy (See Chapters 12 & 13 for Results and Discussion)

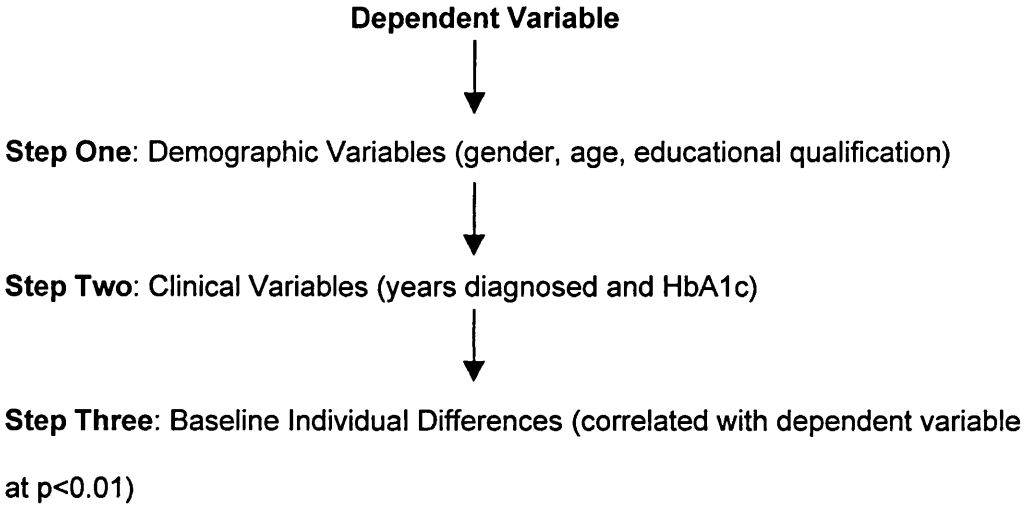
The final analysis conducted on the data set was exploration of whether baseline characteristics of participants could be used to predict benefit from the SMI. Only the intervention group were included in this analysis and prediction of outcome and process variables at each follow-up was explored.

To conduct the predictor analysis residualised change scores were calculated. Residualised change scores were used for the reasons described in section 5.7.4 and have previously been used in analysis of similar datasets (Sinclair & Wallston, 2001).

Correlation analysis was performed between residualised change scores and baseline variables and used to inform entry into regression analysis. Regression analysis was conducted on the residualised change scores of any variable that showed association with baseline characteristics at $p<0.01$. The criteria of $p<0.01$ for significant association was selected because of the large number of correlations performed, and hence risk of a type 1 error. For all analysis demographic variables (gender, age, and educational qualification) were forced into the equation at step one. At step two clinical variables (years diagnosed and HbA1c) were forced into the equation. These variables were forced into the equations to allow for examination of the extent that demographic and clinical variables can be used to predict benefits of the SMI. At step three any baseline

variables that were significantly associated with the dependent variable were entered into the regression analysis. If independent variables identified for entry into the regression analysis were significantly associated at $p<0.01$ then issues of multicollinearity were considered and where appropriate selection between variables to be entered was made. Figure 5.3 shows the order of entry into regression analysis.

Figure 5.3 – Entry of Variables into Regression Analysis for Prediction of Intervention Efficacy



CHAPTER SIX: BASELINE CHARACTERISTICS OF THE STUDY SAMPLE

6.1 Structure of the Chapter

The current chapter provides an overview of participant characteristics at baseline. The chapter begins with a description of recruitment into the study including numbers allocated to each group and reasons given for non-participation in the trial. Reliability and validity statistics for each measure used in the study are then provided and rationale given for those scales felt to be inappropriate for further evaluation. Descriptive data for the study sample on outcome and process variables are then provided, as are correlation analyses between demographic, outcome and process variables. This data allows for consideration of whether relationships in the current study sample are comparable to previous research.

6.2 Recruitment of Study Sample

Two hundred and forty five participants met inclusion/exclusion criteria and were approached to take part in the study. Of these 134 (54.7%) agreed to participate, including 7 individuals who were involved in piloting of the manual (data from these 7 individuals was not included in the final analysis). After six months of recruitment only 3 individuals allocated to immediate intervention, had selected to attend the social support programme. Due to the lack of interest and the probability of not achieving sufficient power in the social support arm of the study this arm was closed and analysis pertaining specifically to differences in social support behaviours between groups was not performed. Within the other two arms of the study 65 participants were recruited to the SMI attended alone arm and 59 participants were recruited to the standard treatment control arm. The total study sample was therefore 124 participants over two groups.

Of those individuals who were not willing to take part in the study a number of reasons were given as shown in table 6.1. It is of note that 18 participants reported interest in attending a SMI in the future but could not commit to a randomisation process that may have required attendance at sessions in the near future. Comparison of participants who accepted and rejected the intervention indicated that there were no significant differences on gender, age or years since diagnosis (see appendix 3).

Table 6.1 Reasons Given for Non-Participation in the Research Trial

Reason Given for Non-Participation	**Number of Participants**
Not interested in a self-management intervention	33
Too busy / work commitments	28
Currently unwell	10
Live too far from hospital	8
Felt diabetes to be under control	7
Other	7
Would be interested in future	18
Total Number of Individuals Approached	**245**

6.3 Data Exploration

Following data cleaning (see chapter 5, section 5.7.1) internal reliabilities for all scales with more than two items and using the complete sample were calculated (see table 6.2). A Cronbach's alpha of greater than 0.70 was used as the acceptable criterion to

indicate reliability, and has been recommended for studies involving groups of patients (Fitzpatrick, Davey, Buxton & Jones, 1998). Not all sub-scales achieved this criterion. For example in the revised SDSCA scale the specific dietary sub-scale had poor reliability (α = 0.08). Low reliability on this sub-scale has been reported in previous studies and it has been recommended (Toobert *et al.,* 2000) that the two specific dietary items relating to consumption of fruit and vegetables and consumption of fat be analysed separately, hence this is the method adopted in the current study. Cronbach's alphas for both exercise behaviour and foot-care behaviour sub-scales also fell below the level desired, which may in part be due to the small number of items comprising the scales. Given the importance of exercise as an outcome this sub-scale was retained, however the foot-care behaviour subscale was dropped from further analysis, as this was not a primary focus of the current intervention.

Reliability analysis of all QoL and psychological well-being measures were acceptable as were measures of knowledge, self-efficacy, generalised social support and beliefs about seriousness of diabetes and treatment effectiveness. Within the personal models of diabetes measure, the control sub-scale indicated low reliability hence the single item " how much control do you feel you have over your blood sugar levels?" was used for this subscale. Finally the diabetes specific social support measure indicated consistently poor reliability on all but one sub-scale. Given the poor reliability of this scale, and the fact that the social support intervention was no longer being assessed, and hence was not a primary outcome, this scale was also dropped from further analysis. Sub-scales that were retained for further analysis are indicated with an (*) in table 6.2

Table 6.2 Scale Reliabilities for Outcome and Process Scales Included in the Current Study

Measure (including sub-scales)	Number of items	Cronbach's alpha
Revised SDSCA Scale (n=124)		
General Diet*	2	0.94
Specific Diet†	2	0.08
Exercise*	2	0.64
SMBG*	2	0.94
Foot-Care	2	0.45
ADDQoL (n=124)*	13	0.89
SF-36 (n=122)		
Physical Functioning	10	0.88
Role Physical	4	0.88
Role Emotional	3	0.90
Social Functioning	2	0.76
Mental Health	5	0.71
Energy/Vitality	4	0.81
Pain	2	0.76
General Health	5	0.70
Physical Composite Scale*	na	na
Mental Composite Scale*	na	na
HAD Scale (n=116)		
Depression*	7	0.77
Anxiety*	7	0.78
PANAS(n=114)		
Negative Affect*	5	0.73
Positive Affect*	5	0.84
MDRTC Knowledge (n=119)*	14	0.68
Self-Efficacy Scale (n=119)*	7	0.82

Measure (including sub-scales)	Number of items	Cronbach's alpha
Personal Models of Diabetes (n=124)		
Seriousness*	3	0.60
Treatment Effectiveness*	6	0.78
Control†	2	0.06
DFBC-II (n=95)		
Diet	4	0.46
Exercise	3	0.52
SMBG	2	0.62
Medication	2	0.36
Positive Support	8	0.72
Negative Support	6	0.58
MSPSS (n=112)		
Significant Other*	4	0.91
Family*	4	0.93
Friend*	4	0.87
Total*	12	0.92

* sub-scale included in analysis of data † individual items used in preference to sub-scale

6.4 Characteristics of Study Sample at Baseline

Comparison of intervention and control group participants was conducted on all outcome and process measures at baseline.

6.4.1 Demographic Variables

6.4.1.1 Characteristics and Differences Between Groups on Demographic Variables - Table 6.3 shows demographic characteristics of the sample. The mean age of participants was 60 years with an age range of between 40 and 76 years. The majority (71%) of participants were male. Ethnicity was originally categorised into six groups (Caucasian, Black African, Black Caribbean, Asian, Oriental, Other) however due to the

small number of participants in certain groups i.e. Black African (n=9) and Oriental (n=2) these latter two groups were collapsed with Black Caribbean and Asian respectively to form a total of four groups. In addition a separate group for individuals from Mediterranean countries was formed. Although such individuals could be classified as Caucasian this distinction was made because a relatively high proportion of participants were either of Greek or Cypriot origin and it was of interest to see whether this group responded differently to the intervention.

Table 6.3 Demographic Characteristics of Study Participants at Baseline

	Total n=124	Control n=59	SMI n=65	Statistical Significance
Age (yrs) (mean ± s.d)	59.73±8.7	60.28±8.6	59.21±8.8	t (0.66, df =122) P=0.49
Gender (% Male)	71.0	74.6	67.7	χ^2 (7.11,df =1), p=0.40
Ethnicity (%) – Caucasian (British)	37.1	33.9	40.0	χ^2 (1.37,df =3), p=0.71
Black African/Caribbean	26.6	25.4	27.7	
Asian	24.2	28.8	20.0	
Mediterranean	12.1	11.9	12.3	
Marital Status (%) – Married/cohabiting	63.6	57.9	68.8	χ^2 (3.14, df =2), p=0.21
Divorced/widowed	19.8	19.3	20.3	
Single	16.5	22.8	10.9	
Employment (%) – Retired	57.7	58.6	56.9	χ^2 (3.25,df =2), p=0.19
Employed	30.1	34.5	26.2	
Unemployed/Other	12.2	6.9	16.9	
Education (%) - No Qualifications	39.7	39.7	39.7	χ^2 (0.09, df =3), p=0.99
O Level equivalent	21.6	22.4	20.7	
A Level equivalent	14.7	13.8	15.5	
Graduate	24.1	24.1	24.1	

Comparison of control and SMI groups on continuous data was by t-test, comparison of categorical data was by chi-square analysis.

The spread across ethnic groups was high with approximately two thirds of the population being from groups other than British Caucasian. The majority of individuals were either married or cohabiting, were retired and over one third of the population had obtained no educational qualifications. There were no significant differences between intervention and control groups on any of the demographic measures.

6.4.2 Clinical Variables

6.4.2.1 Characteristics and Differences Between Groups on Clinical Variables - The clinical characteristics of participants are shown in table 6.4. Participants had been diagnosed with diabetes for between 1 and 30 years with a mean duration of 10.8 years. Self-reports of complications showed that individuals had an average of three diabetes related complications. Microalbuminuria was diagnosed for all participants and 80% of individuals reported having hypertension. The mean HbA1c level for all individuals was 8.6% with the majority of individuals treated by oral hypoglycaemic tablets alone. There were no significant differences between the intervention and control group on any of these clinical characteristics.

6.4.2.2. Relationships Between Clinical Variables at Baseline - Correlations between clinical variables indicated no significant associations between duration of diabetes, diabetes complications or HbA1c (see appendix 5 for full correlation matrix of baseline variables). Longer duration of diabetes was however significantly associated with higher systolic blood pressure ($r=0.35$, $p<0.001$) although not diastolic blood pressure. Baseline HbA1c was significantly different depending on medication type with those individuals taking tablets and insulin having poorer HbA1c values than either those just following diet and exercise advice or only taking tablets ($F(3,116) = 3.78$, $p<0.05$). Individuals taking tablets and insulin also had been diagnosed with diabetes for a longer

duration than individuals only treated with diet and exercise advice ($F(3,117) = 4.48$, $p<0.01$).

Table 6.4. Clinical Characteristics of Study Participants at Baseline

	Total N=124	Control N=59	SMI N=65	Statistical Significance
Duration (yrs) (mean ± s.d.)	10.77±7.7	10.87±7.9	10.67±7.5	t(0.15, df =120) p=0.88
Diabetes related complications (mean ± sd.)	2.68±0.9	2.55±0.9	2.80±1.1	t(-1.34,df =122) p=0.18
HbA1c (mmol/l) (mean ± s.d.)	8.61±1.8	8.71±1.8	8.52±1.7	t(0.59,df =121) p=0.55
Blood Pressure (mean ±sd)				
SBP (mmHg)	144.72±18.8	146.3±20.6	142.9±16.5	t(0.86,df=90) p=0.39
DBP (mmHg)	83.47±11.8	83.56±13.2	83.37±10.1	t(0.08,df=89) p=0.94
Diabetes Medication %				χ^2 (4.29,df =3), p=0.23
Diet/Exercise	9.9	15.5	4.8	
Tablets	66.1	62.1	69.8	
Insulin	10.7	8.6	12.7	
Tablets &Insulin	13.2	13.8	12.7	

Comparison of control and SMI groups on continuous data was by t-test, comparison of categorical data was by chi-square analysis.

6.4.3 Self-Management Behaviours

6.4.3.1 Characteristics and Differences Between Groups on Self-Management - The frequency of individual self-management behaviours, i.e. the number of days per week the behaviour was performed (range 0-7) is shown in table 6.5. Following a healthy diet was the behaviour reportedly performed the most frequently. Of the specific dietary behaviours not eating high fat foods was reported more frequently than the consumption of five or more pieces of fruit and vegetables a day. Exercise was the behaviour followed least frequently, with individuals taking exercise less than three days a week on

average. Approximately one third of participants did not test blood glucose at baseline; of those that did, 3 days per week was the mean frequency. The majority of participants were non-smokers with only 22 individuals reporting being smokers at baseline. The number of cigarettes smoked per day ranged from 1-70 with a mean of 22. Frequency of self-management behaviours at baseline did not vary significantly between the control and intervention groups for any aspects of the regimen.

Table 6.5. Frequency of Self-Management Behaviours of Study Participants at Baseline

	Total n=124 (mean ± sd)	Control n=59 (mean ± sd)	SMI n=65 (mean ± sd)	Statistical Significance
General Diet	4.98±2.1	5.14±2.2	4.82±2.0	t(0.86,df =122) p=0.39
Fruit & Veg Cons	3.98±2.9	4.10±3.0	3.86±2.9	t(0.45,df =122) p=0.65
Fat Cons.	4.94±2.1	5.17±1.8	4.72±2.3	t(1.20,df =122) p=0.23
Exercise	2.51±2.3	2.87±2.3	2.18±2.2	t(1.72,df =122) p=0.09
BG Monitoring	3.04±2.9	2.75±2.7	3.29±3.0	t(-1.04,df =122) p=0.30
% Non-Smokers	82.3	78.0	86.2	χ^2(1.42,df =1), p=0.23

Comparison of control and SMI groups on continuous data was by t-test, comparison of categorical data was by chi-square analysis.

6.4.2.2. Relationships Between Self-Management Behaviours at Baseline – Correlation analyses between self-management behaviours (see table 6.6) showed that general dietary behaviour was significantly associated with all other self-management behaviours. The strongest relationship was between general dietary behaviour and consumption of five or more pieces of fruit and vegetables daily ($r=0.30$, $p<0.001$). The two dietary specific self-management behaviours were not significantly associated, however higher consumption of fruit and vegetables was significantly associated with increased exercise ($r=0.29$, $p<0.05$). Avoidance of a high fat diet and SMBG were not

significantly associated with any self-management behaviours other than general dietary behaviour.

Table 6.6. Pearson R Correlation Coefficients for Self-Management Behaviours at Baseline

	1	2	3	4
1. General Diet				
2. Fruit	0.304***			
3. Fat	0.189*	-0.047		
4. Exercise	0.228*	0.289*	-0.091	
5. SMBG	0.204*	0.096	0.020	-0.125

Data indicates Pearson R correlation coefficients * p<0.05, **p<0.01, ***p<0.001

6.4.4 Quality of Life

6.4.4.1 Characteristics and Differences Between Groups on Quality of Life - Generic (SF-36) and diabetes specific (ADDQoL) QoL scores were comparable for both groups (see table 6.7). No significant differences were observed between the groups.

The negative rating on the total weighted ADDQoL score indicated that individuals believed their QoL would be better if they did not have diabetes. This was also reflected in the single item of the scale asking whether an individual's QoL would be better/worse/the same if they did not have diabetes. The general QoL item of this scale however reflected that the mean rating of present QoL was good.

The generic quality of life measure, the SF-36 evaluated 8 components of QoL, which were also combined into two composite scales, physical composite scale (PCS) and mental composite scale (MCS). Individuals reported higher scores for the mental rather

than physical health aspects of QoL with mental health and physical functioning being the dimensions with the highest and lowest means respectively.

Table 6.7 Quality of Life Characteristics of Study Participants at Baseline

	Total (mean ± sd)	Control (mean ± sd)	SMI (mean ± sd)	Statistical Significance
ADDQoL (n=124)				
Weighted Total	-2.62±2.1	-2.67±2.1	-2.57±2.1	t(-0.27,df =122) p=0.79
Single Item General qol	1.00±1.3	1.10±1.4	0.91±1.3	t(0.83,df =122) p=0.41
Single item Diabetes qol	-1.56±1.2	-1.42±1.3	-1.68±1.1	t(1.18, df =122) p=0.24
SF-36 (n=122)				
Physical Functioning	39.47±13.1	40.24±12.7	38.75±13.4	t(0.63,df =120) p=0.53
Role Physical	41.93±13.8	41.43±14.6	42.41±13.2	t(-0.39,df =120) p=0.70
Role Emotional	48.58±11.9	49.15±11.4	48.04±12.5	t(0.51, df =120) p=0.61
Social Functioning	45.84±11.8	45.83±11.8	45.85±11.9	t(-0.01, df= 120) p=0.99
Mental Health	52.09±8.7	53.02±8.3	51.22±9.0	t(1.15, df =120) p=0.25
Energy/Vitality	46.84±10.9	48.39±10.9	45.39±10.9	t(1.15,df =120) p=0.13
Pain	43.88±13.0	44.03±12.3	43.74±13.7	t(0.13, df =120) p=0.90
General Health	41.86±11.4	43.19±11.4	40.61±11.3	t(1.25,df =120) p=0.21
PCS	38.40±12.9	38.59±12.6	38.23±13.3	t(0.16, df =120) p=0.88
MCS	52.05±8.5	53.03±8.4	51.12±8.5	t(1.25,df =120) p=0.21

Comparison of control and SMI groups was by t-test

6.4.3.2. Relationships Between Quality of Life Measures at Baseline - No significant correlations were found amongst the general QoL item from the ADDQoL and either the single diabetes specific QoL item or weighted total of the ADDQoL. The single diabetes specific item in the ADDQoL and weighted total were significantly correlated ($r=0.60$, $p<0.01$). All subscales of the SF-36 were significantly associated with each other and with both SF-36 composite scales (see table 6.8). Better QoL on one sub-scale was associated with better QoL on another. All subscales except for that assessing pain were also significantly associated with the ADDQoL weighted total and single diabetes specific QoL item, but not with the single general QoL item from the ADDQoL.

Given the large number of subscales measuring QoL and the consistency between scales only the ADDQoL weighted total and the SF-36 PCS and MCS were retained for further analyses.

Table 6.8 Pearson R Correlation Coefficients for Quality of Life Measures at Baseline

	1	2	3	4	5	6	7	8	9	10	11	12
1. ADDQoL (tot)												
2. ADDQoL SI gen	-.05											
3.ADDQoL SI diab	.60***	1.00										
4.PF	.40***	.05	.38***									
5.RP	.28**	-.02	.37***	.64***								
6.RE	.41***	-.02	.27**	.43***	.59***							
7.SF	.47***	-.03	.38***	.55***	.58***	.63***						
8.MH	.24**	-.02	.22*	.40***	.33***	.47***	.50***					
9.EV	.23*	-.02	.20*	.65***	.55***	.39***	.55***	.49***				
10.P	.18	-.15	.03	.54***	.53***	.53***	.47***	.41***	.49***			
11.GH	.33***	-.02	.31***	.55***	.60***	.39***	.57***	.43***	.63***	.43***		
12.PCS	.33***	-.04	.31***	.87***	.83***	.48***	.62***	.32***	.68***	.76***	.73***	
13.MCS	.36***	-.02	.27**	.32***	.42***	.78***	.73***	.78***	.59***	.37***	.45***	.32***

SI- single item, Data indicates Pearson R correlation coefficients * p<0.05, **p<0.01, ***p<0.001

6.4.5 Psychological Well-Being

6.4.5.1 Characteristics and Differences Between Groups on Psychological Well-Being - The HAD Scale was used to evaluate depression and anxiety. Mean scores on both subscales fell within the not clinically relevant range of 0-7 (Zigmond & Snaith, 1983) (see table 6.9). For the depression subscale 109 individuals (94%) scored 7 or less

indicating no evidence of clinical depression, 4 individuals (3.4%) scored between 8-10, rated as a possible indicator of clinical depression, and 3 individuals (2.6%) scored 11 or greater and hence were considered to probably have clinical depression. For anxiety 92 individuals (79.3%) scored less than 7, seventeen participants (14.7%) scored between 8-10 rated as an indicator of possible clinical disorder, while 7 (6%) scored 11 or greater and hence were considered as having clinically relevant levels of anxiety. Categorisations for both anxiety and depression were taken from Zigmond & Snaith, (1983). For both depression and anxiety different levels of anxiety and depression were distributed approximately evenly between both the control and SMI groups.

Table 6.9 Psychological Well-Being Characteristics of Participants at Baseline

	Total (mean ± sd)	Control (mean ± sd)	SMI (mean ± sd)	Statistical Significance
HAD Scale (n= 116)				
Depression	3.27±3.1	3.17±2.5	3.36±3.6	t(-0.33,df = 114) p=0.74
Anxiety	4.47±3.5	4.67±3.2	4.81±3.8	t(-0.21, df =114) p=0.83
PANAS (n=114)				
Positive affect	13.10±5.3	13.18±5.7	13.02±4.9	t(0.16, df =112) p=0.87
Negative affect	8.23±3.5	8.13±3.0	8.33±4.0	t(-0.31, df =112) p=0.76

Comparison of control and SMI groups was by t-test,

Negative affect and positive affect were measured by the short form PANAS. Both the SMI and control group scored higher for positive than negative affect, but no differences were identified between groups.

6.4.4.2. Relationships Between Psychological Well-Being Measures at Baseline

The three measures of negative mood (depression, anxiety and negative affect) were all significantly correlated (see table 6.10). Depression showed no significant association

with positive affect however both higher anxiety and negative affect were significantly associated with positive affect such that the higher anxiety and negative affect the higher positive affect.

Table 6.10 Pearson R Correlation Coefficients for Psychological Well-Being at Baseline

	1	2	3
1.HAD Depression			
2.HAD Anxiety	.60***		
3.PANAS Positive affect	-.06	.29**	
4.PANAS Negative affect	.38***	.58***	.27**

Data indicates Pearson R correlation coefficients * p<0.05, **p<0.01, ***p<0.001

6.4.6 Process Variables

6.4.6.1 Characteristics and Differences Between Groups on Process Variables - Mean scores for each of the process variables are shown in table 6.11. For knowledge participants accurately reported just over half of the multiple-choice questions they were asked correctly. For self-efficacy participants were most confident in their ability to test and control their blood sugars and had less confidence in their ability to exercise and follow dietary plans. Participants reported being most prepared to change their diet or the amount they tested blood glucose if advised to do so by their diabetes team. Scores for personal models of diabetes indicated that on average participants thought their diabetes was fairly serious, treatment was 'moderately effective', and they had 'fair control' over their diabetes. Overall participants reported high levels of social support, which was relatively comparable between sub-scales of the MSPSS. There were no significant differences between the control and SMI groups on any process variable at baseline.

Table 6.11 Characteristics of Study Participants on Process Variables at Baseline

	Total (mean ± sd)	Control (mean ± sd)	SMI (mean ± sd)	Statistical Significance
Knowledge (n=119)	56.24±20.3	54.24 ±20.5	58.21 ±20.1	t(-1.07,df=117) p=0.29
Self-Efficacy (n= 119)				
Total	69.11±18.9	69.76±19.5	68.47±18.5	t(0.37,df =117)p=0.71
Diet	68.51±24.6	68.90±26.0	68.15±23.4	t(0.17,df =119) p=0.87
Exercise	59.17±32.0	61.19±31.6	57.21±32.6	t(0.68,df =118) p=0.50
SMBG	82.16±22.5	80.09±22.9	84.39±22.1	t(-0.96,df =100) p=0.34
Personal Models (n=124)				
Seriousness	3.00±0.9	2.96±0.9	3.04±0.9	t(-0.52,df =122) p=0.61
Treat. Effectiveness	3.85±0.6	3.81±0.6	3.87±0.6	t(-0.57,df =122) p=0.57
Control	3.18±0.9	3.19±0.9	3.17±0.9	t(0.10,df =122) p=0.92
RTC (n= 120)				
Diet	6.21±1.1	6.30±1.0	6.12±1.2	t(0.88,df =118) p=0.38
Exercise	5.80±1.5	5.85±1.5	5.75±1.5	t(0.39, df =118) p=0.70
SMBG	6.19±1.2	6.15±1.4	6.24±1.1	t(-.40, df =118) p=0.69
Medication	5.68±1.9	5.51±1.9	5.86±1.7	t(-1.05, df =118) p=0.30
Social Support (n=112)				
Significant Other	5.68±1.84	5.96±1.55	5.41±2.06	t(1.58, df =110) p=0.12
Family	5.35±1.98	5.29±1.98	5.40±2.00	t(-0.31,df =110)p=0.76
Friends	5.21±1.55	5.50±1.46	4.94±1.60	t(1.94, df =110) p=0.06
Total	5.41±1.48	5.58±1.29	5.25±1.64	t(1.18, df =110) p=0.24

Comparison of control and SMI groups was by t-test,

6.4.6.2. Relationships Within Process Measures at Baseline - Full correlation analysis between process measures is reported in appendix 5. Higher self-efficacy for diet was significantly associated with higher self-efficacy for both SMBG ($r=0.22$, $p<0.05$) and exercise ($r=0.48$,$p<0.001$). The correlation between self-efficacy for exercise and SMBG was not significant ($r=0.05$, $p=0.63$).

Stronger beliefs in treatment effectiveness were significantly associated with belief in the seriousness of diabetes ($r=0.34$, $p<0.001$) and sense of control over blood glucose ($r=0.35$, $p<0.001$) such that the stronger an individual believed in the seriousness of diabetes the greater their sense of control over blood glucose. There was however no significant association between belief in seriousness of diabetes and sense of control ($r=0.16$, $p=0.07$).

Generally, high RTC in one behaviour was significantly correlated with high RTC in another behaviour as shown in table 6.12. The exception to this was RTC exercise and RTC SMBG, which were not significantly correlated.

Table 6.12 – Pearson R Correlation Coefficients for RTC Self-Management Behaviours at Baseline

	1	2	3
1.RTC Diet			
2.RTC SMBG	0.317***		
3.RTC Exercise	0.554***	0.155	
4.RTC Medication	0.300***	0.379***	0.203*

Data indicates Pearson R correlation coefficients * $p<0.05$, ** $p<0.01$, *** $p<0.001$

All social support scales were significantly correlated such that higher support in one domain was associated with higher support in other domains. Pearson R correlations ranged between $r= 0.38$ to $r= 0.89$ for this scale.

6.5 The Relationships between Demographic, Outcome and Process Variables at Baseline

Association between demographic, outcome and process variables were conducted to further explore the data. A full correlation matrix is provided in appendix 5. Due to the large number of correlations and hence risk of a type 1 error only associations significant at $p<0.01$ are reported. Where variables were categorical analysis was by t-test or Chi-Square as appropriate.

6.5.1 Factors Significantly Related to Clinical Variables

Older individuals had been diagnosed with diabetes for a longer period ($r=0.26$, $p<0.01$) and had more complications ($r=0.24$, $p<0.01$) than younger individuals, however age was not significantly associated with glycaemic control ($r=-0.17$, $p=0.06$), SBP ($r=0.20$, $p=0.05$) or DBP ($r=-0.06$, $p=0.56$). Glycaemic control was not significantly correlated to any outcome or process variable.

6.5.2 Factors Significantly Related to Self-Management Behaviours

Demographic and clinical variables were not significantly related to self-management behaviours with the exception of education level and exercise ($p<0.001$). Individuals who had been educated to 'A level standard' or above were more likely to exercise than individuals with no qualifications.

Neither diabetes specific (ADDQoL weighted total) nor generic QoL (SF-36 composite scales) were significantly correlated with self-management behaviours. Negative well-being (i.e. depression, anxiety, negative affect) was not significantly associated with self-management behaviours. Positive affect was however significantly associated with both frequency of fruit and vegetable consumption ($r=0.26$, $p<0.01$) and exercise ($r=0.28$,

p<0.01), with higher levels of both self-management behaviours associated with higher positive affect.

A number of process variables were significantly related to self-management behaviours. Knowledge scores were significantly associated with consumption of fruit and vegetables (r=0.245, p<0.01), such that individuals with greater knowledge consumed five items of fruit and vegetables more frequently. The composite self-efficacy score was significantly correlated with general dietary behaviours (r=0.57, p<0.001), consumption of fat (r=0.24, p<0.01) and exercise (r=0.30, p<0.01), such that the higher self-efficacy the greater frequency with which the behaviour was reported. Higher correlations however were typically seen between behaviours and the behaviour specific self-efficacy items than with composite self-efficacy (see table 6.13).

Table 6.13 – Pearson R Correlation Coefficients for Self-Management Behaviours and Self-Efficacy at Baseline

	Composite Self-Efficacy	Dietary Self-Efficacy	Exercise Self-Efficacy	SMBG Self-Efficacy
General Diet	0.569***	0.644***	-	-
Fruit & Veg Consumption	0.222*	0.248**	-	-
Fat Consumption	0.242*	0.216*	-	-
Exercise	0.300***	-	0.566***	-
SMBG	0.161	-	-	0.384***

Data indicates Pearson R correlation coefficients * p<0.05, **p<0.01, ***p<0.001

Treatment effectiveness was the belief most consistently associated with self-management behaviours. This was significantly associated with fruit and vegetable consumption (r=0.32, p<0.001) and SMBG (r=0.25, p<0.01) hence higher beliefs in

treatment effectiveness were related to more frequent performance of behaviour. Non-smokers also had a higher belief in treatment effectiveness than smokers. Greater belief in the seriousness of diabetes was significantly associated to more frequent SMBG ($r=0.25$, $p<0.01$). Greater belief in control over blood glucose was significantly correlated to more frequent following of a generally healthy diet ($r=0.27$, $p<0.01$).

RTC exercise was significantly associated with exercise ($r=0.25$, $p<0.01$) and RTC SMBG was significantly associated with frequency of SMBG ($r=0.27$, $p<0.01$). The more ready an individual was to change these behaviours the more frequently the behaviours were performed. Social support was not significantly associated with any self-management behaviours at baseline.

6.5.3 Factors Significantly Related to Quality of Life and Psychological Well-Being

Gender was the only demographic factor to be related to quality of life and psychological well-being. Female participants reported significantly poorer QoL on the SF-36 PCS and significantly higher negative affect on the PANAS.

The more complications an individual had the poorer both diabetes specific QoL ($r=-0.26$, $p<0.01$) and the SF-36 PCS ($r=-0.30$, $p<0.01$). Diastolic blood pressure was not significantly associated with diabetes QoL, depression, negative affect or positive affect, however higher systolic blood pressure was significantly associated with anxiety ($r=-0.40$, $p<0.001$) such that the higher anxiety at baseline the lower SBP.

The relationships between QoL and psychological well-being to self-management behaviours has been reported above (see section 6.5.2).

Both generic and diabetes specific QoL were significantly associated with negative aspects of psychological well-being (see table 6.14) including depression, anxiety and negative affect such that poorer well-being scores were associated with lower QoL. None of the QoL scales were significantly associated with positive affect.

Table 6.14 – Pearson R Correlation Coefficients for Quality of Life and Psychological Well-Being at Baseline

	ADDQoL	PCS SF-36	MCS SF-36
Depression	-0.344***	-0.451***	-0.535***
Anxiety	-0.297***	-0.355***	-0.545***
Negative Affect	-0.265**	-0.313***	-0.661***
Positive Affect	-0.036	0.041	-0.099

Data indicates Pearson R correlation coefficients * $p<0.05$, ** $p<0.01$, *** $p<0.001$

The only significant association between diabetes specific QoL and process measures was with belief in seriousness of diabetes. The negative association ($r=-0.526$, $p<0.01$) indicated that higher belief in seriousness was related to poorer quality of life. This relationship was replicated for both SF-36 MCS ($r=-0.431$, $p<0.001$) and SF-36 PCS ($r=-0.327$, $p<0.001$). In contrast both anxiety ($r= 0.33$, $p<0.001$), depression ($r=0.36$, $p<0.001$) and negative affect ($r=0.30$, $p<0.001$) were positively associated with belief about the seriousness of diabetes, hence higher belief in seriousness was related to higher negative affect and anxiety. Other significant associations between QoL, psychological well-being and process measures included a significant association between the SF-36 PCS and belief in control over blood glucose ($r=0.30$, $p<0.001$). Greater belief in control over blood glucose was associated with better QoL. Depression was negatively correlated with the total self-efficacy scale ($r=-0.31$, $p<0.001$) such that higher depression was associated with lower self-efficacy. Depression was

also negatively associated with social support from significant others (r=-0.27, p<0.01), friends (r=-0.28, p<0.01) and the total social support scale (r=-0.29, p<0.01). Higher levels of depression were associated with lower social support. Positive affect was significantly associated with knowledge such that greater knowledge was associated with greater positive affect (r=0.38, p<0.01).

6.5.4 Relationships Between Process Variables

The relationships between process variables and other outcomes have been presented above. Relationships between process measures indicated that higher knowledge was significantly associated with a greater belief in treatment effectiveness (r=0.343, p<0.01). Composite self-efficacy was significantly associated with belief in control over blood glucose (r=0.38, p<0.001), RTC diet (r=0.26, p<0.01) and RTC exercise (r=0.26, p<0.01), social support from significant others (r=.28, p<0.01) and total social support (r=.28, p<0.01). Self-efficacy for diet was significantly associated to RTC diet (r=0.24, p<0.01), belief in control over blood glucose (r=.28, p<0.01) and social support from significant others (r=.26,p<0.01). Self-efficacy for exercise was significantly associated with RTC exercise (r=0.41, p<0.01). Finally total social support and all sub-scales of the MSPSS were significantly correlated with RTC dietary behaviour (r = 0.30-0.39, p<0.001).

CHAPTER SEVEN: DISCUSSION OF BASELINE CHARACTERISTICS OF THE STUDY SAMPLE

7.1 Structure of Chapter

The current chapter discusses the results presented in chapter six. It begins by considering whether the recruited sample was representative of the population from which they were drawn. Reasons for study refusal and uptake rate relative to other studies are also discussed.

Furthermore as the current study selected a specific type 2 diabetes population, (i.e. individuals with microalbuminuria or proteinuria) specific characteristics of the sample are discussed and compared to previous research. The implications of this regarding the generalisability of the study to the broader population of individuals with type 2 diabetes are presented.

7.2 Representativeness of the Study Sample

A participation rate of 54% was achieved in the current study. Comparison of those individuals who declined to take part in the study and those who agreed indicated that there was no difference in basic demographic or clinical measures including gender, age and duration of diabetes. This implies that participants recruited into the study were representative of the population being sampled as far as these measures are concerned.

Participation rates in other self-management studies with patients with type 2 diabetes vary between 32%-100%, with a median rate of 73% (Glasgow, Eakin, & Toobert, 1996). It could be expected that the intensity and time demands of an intervention influence an individual's likelihood of choosing to participate. For example in a 2 year intensive self-

management intervention by Toobert, Strycker, Glasgow & Bagdade, (2002) participation was approximately 51%, while a brief intervention by Glasgow *et al.,* (1996) and Clark, Hampson, Avery, & Simpson, (2004) reported higher participation rates of 61% and 60.2% respectively. Given that the intensity of the current study fell between these studies the participation rate of the current study can be considered comparable to other similar studies.

It is important however that the population selected for this study (i.e. those with microalbuminuria or proteinuria) may have been expected to feel that self-management was particularly important. That participation rates were not higher may suggest this was not the case. Significantly the view that self-management would be important to this group was given by clinicians and the assumption that this view would be reflected by individuals with type 2 diabetes and microalbuminuria may have been incorrect. This issue is further confounded by the fact that the facilitators of the programme reported that a number of participants were not aware of their diagnosis of microalbuminuria.

Of those individuals declining the study the most common reasons given were either lack of interest in the project (29%) or being too busy/too great a time commitment (25%). Being too busy has been reported as a common reason for non-participation in other studies (Toobert *et al.,* 2002; Glasgow *et al.,* 1996). This has important implications for the design and provision of interventions and emphasises the need to consider making interventions less time intensive if participation rates are to be increased. It is important however that the explanation of time-commitments is a socially acceptable reason for non-participation and it may mask more complex and less socially acceptable reasons for declining participation in a research study.

7.3 Were Baseline Characteristics of the Study Sample Consistent with Previous Research?

The aim of the study was not to restrict the sample, aside from the criteria of microalbuminuria or proteinuria, in order to obtain a group as representative of the clinic attendees as possible. Therefore exclusion criteria were limited and the intervention and assessments were offered at varying times of the day to allow both working and non-working individuals to participate. The final sample indicated that this aim was largely achieved, with participants showing diversity on ethnic background and marital, employment and educational status. One area of interest in this sample was the higher percentage of males than females that participated in the study (67.7%). Reviews of the literature have not tended to comment on differential participation by gender (Ellis *et al.,* 2004; Norris *et al.,* 2002a, 2001) hence it is unclear whether these findings are unusual. This may however reflect the sub-sample of individuals (i.e. with microalbuminuria) in this study. The risk of nephropathy is higher in males than females (Ritz & Orth, 1999) hence this may have contributed to the higher participation by males in the current study.

The pattern of self-management behaviours at baseline is not different to previous research, which has indicated that individuals report higher levels of dietary behaviours than exercise behaviour (see for example Clark *et al.,* 2004; Toobert *et al.,* 2002). The absolute levels in the current study, particularly for diet, are however higher than has been reported in two recent studies evaluating self-management behaviours in UK populations and using the SDSCA scale. Clark & Hampson, (2001) reported that diet guidelines were adhered to on average 3.77 days per week, whilst Deakin, (personal communication), reported a healthy diet to be followed on approximately 2.5 days per week. This contrasts to 4.98 days per week for general dietary behaviour in this study.

The higher than expected levels of dietary self-care behaviours in the current study could be explained by three possibilities i) a true reflection of self-management behaviours, ii) an increase in responses due to social desirability, iii) different perceptions of what constitutes a healthy diet between samples. Items asking how frequently a healthful eating plan was followed or high fat foods were avoided requires a view of what constitutes these activities. This is dependent on participant's own perceptions and knowledge and may be discordant with the researchers understanding of what constitutes a healthy diet or high fat food. More importantly different individuals may report different frequencies of following a healthy diet even if objectively there is no difference. Unfortunately as objective measures of self-management were not included in the current study it is not possible to determine the relationship between perceptions of diet and behaviour. This highlights the limitations of self-report measures. (This issue is addressed further in chapter 14).

Correlations between self-management behaviours at baseline ranged from r= –0.09 to r= 0.304. These moderate associations suggest that self-management behaviours should be considered independently, as has been asserted previously in the diabetes literature (Glasgow *et al.,* 1989; Ary *et al.,* 1986). It is of note that the specific dietary behaviours of fruit and fat consumption were not significantly correlated, suggesting that even within one behavioural dimension such as diet, behaviours should be treated independently. It was on this basis that in the results the 'specific diet' sub-scale of the revised SDSCA scale was disregarded and preference given to the individual dietary items. The lack of association between dietary variables in patients with diabetes has been reported previously (Toobert *et al.,* 2000).

Assessment of quality of life using the ADDQoL suggested that although diabetes had a negative impact on QoL the mean rating of general QoL was good. This is in line with previous research using the ADDQoL (Bradley & Speight, 2002; Woodcock *et al.,* 2001). Overall weighted diabetes QoL in the current sample was poorer (-2.62) than reported by either Woodcock *et al.,* (2001) (-1.8) or Bradley & Speight, (2002) (-1.96) on the same measure. This is however to be expected given that individuals in the current study were diagnosed with at least one complication. The association between diabetes complications and QoL is well established (Rubin and Peyrot, 1999) and was found in this study ($r=-0.26$, $p<0.01$, ADDQoL and diabetes complications).

Scores for QoL as measured by the SF-36, were slightly lower than has previously been reported when the SF-36 has been used with individuals with diabetes in the UK (Roberts, Hemingway & Marmot, 1997; Woodcock *et al.,* 2001). As with diabetes specific QoL this is likely to be due to the number of complications experienced by individuals in the current sample. Other characteristics of the SF-36 in the current population such as significant correlations between sub-scales and low scores on the general health sub-scale are consistent with previous studies (Roberts *et al.,* 1997; Woodcock *et al.,* 2001). The SF-36 PCS and SF-36-MCS indicated that the current sample had poorer QoL than the general population, particularly on the physical components of the SF-36, which again is consistent with previous research (Rubin & Peyrot, 1999).

The mean scores for both anxiety and depression in the current sample were in the non-clinical levels, however approximately 3% of individuals had a score indicative of possible clinical depression and 3% of individuals had scores indicative of probable clinical depression. For anxiety 15% of individuals reported symptoms indicative of

possible anxiety disorder and a further 6% had scores reflective of probable clinical disorder. These findings are in contrast to other reports of mood disorders assessed by self-report tools in people with diabetes (31% and 40% for depression and anxiety respectively (Anderson *et al.,* 2001; Grigsby *et al.,* 2002). The lower levels of clinical depression and anxiety in the current study may be due to self-selection. It can be hypothesised that individuals suffering from clinical anxiety or depression would be less likely to take part in an interventional research project addressing self-management.

The associations between depression, anxiety and negative affect were significant and as expected. The significant correlation between positive affect and both anxiety and negative affect, such that higher positive affect was related to higher anxiety and negative affect, was however unexpected. The reason for this is unclear but could reflect a tendency for some individuals to endorse all mood states to the same degree without differentiating between negative and positive affect. Because of this unusual finding any of the results involving positive affect must be treated with caution.

Of the process measures it is notable that knowledge scores for the current sample were low, with a mean of just over half (56%) of questions answered correctly. These scores correspond to those achieved by individuals with the lowest educational levels in a study by Fitzgerald *et al.,* (1998). Poor knowledge and low levels of diabetes education have previously been identified as a problem in the UK (Naqib *et al.,* 2002; Audit Commission, 2000) and highlighted the need for more SMIs within the UK.

Overall level of self-efficacy in the current study was similar to that reported previously (Talbot *et al.,* 1997) as was the finding that self-efficacy was highest for SMBG and lowest for exercise (Williams & Bond, 2002). The difference in self-efficacy between

behaviours reinforces the importance of considering both general self-efficacy and specific self-efficacy for particular behaviours. The pattern and extent of endorsement of beliefs about diabetes also reflected previous work (Hampson *et al.*, 2000).

In the current study although the diabetes family behaviour checklist was administered it was excluded from the analysis. This measure of social support requires respondents to name a family member whom they have most contact with and answer questions in relation to that individual. In the current study where approximately 36% of individuals were single, widowed or divorced, a number of individuals had difficulty identifying a family member to whom they could relate. In addition where the family member did not live with the respondent (e.g. if they were an adult child) some of the questions were not meaningful (e.g. "how often do you eat at the same time that he/she does?). This later point raised concerns over the validity of the measure. The internal reliability of sub-scales was also found to be poor on 4 out of 6 scales. The authors have reported similar difficulties with internal reliability (Glasgow & Toobert, 1988) but have suggested this may be due to the small number of items per sub-scale. Given the concerns regarding the measure it was felt preferable to exclude this measure from analysis in the current study. This was considered to be a reasonable approach as a second measure of social support the MSPSS demonstrated acceptable psychometric data, and mean scores comparable with previous studies (Zimet *et al.*, 1988). As a result the MSPSS was used as the sole indicator of social support.

7.4 Were Relationships Between Measures at Baseline Consistent with Previous Research?

The extent that relationships between variables are consistent with previous research or theory is an additional indicator of study generalisability. For demographic variables

findings were as expected, for example retired individuals were significantly older than either employed or unemployed individuals. Associations between clinical and demographic variables indicated that divorced or widowed individuals had significantly more complications than married participants. This is consistent with the literature in the general population that married individuals have better health than unmarried individuals (Berkman, & Syme, 1979; Goodwin, Hunt, Key & Sarnet, 1987). The number of complications was also higher for individuals taking tablets and insulin as compared to those only following diet or exercise advice. HbA1c may mediate this relationship, as complications are associated with higher HbA1c levels, and medical management tends to become more aggressive as HbA1c levels increase. This was seen in the current study where use of tablets and insulin was associated with higher HbA1c than either use of just diet and exercise or tablets alone, however this relationship was only found to be significant at $p<0.05$ and hence must be interpreted with caution.

Relationships consistent with previous studies of self-management behaviours included an association between more frequent exercise and higher positive affect, which although examined infrequently in the type 2 population, is established within the general population (Salmon, 2000). Also as would be expected individuals prescribed both tablets and insulin conducted SMBG more frequently than individuals prescribed just diet and exercise or tablets. This is in line with previous research (Bjorsness *et al.,* 2003).

Self-efficacy showed consistent relationships with self-management behaviours and as has been reported previously (Kavanagh *et al.,* 1993; Skelly *et al.,* 1995; William & Bond, 2002) these relationships were strongest when behaviour specific rather than general self-efficacy was assessed. Self-efficacy was also correlated with belief in personal control over diabetes.

Previous research has reported that personal models of diabetes, and in particular belief in treatment effectiveness, are consistently related to self-management behaviours (Hampson *et al.,* 2000; Glasgow *et al.,* 1997). The finding that greater belief in treatment effectiveness in the current study was significantly correlated with diet, SMBG and smoking, is in support of this previous work. A greater belief in seriousness of diabetes was also associated with poorer QoL and higher negative affect, which replicates the findings of Hampson *et al.,* (1995, 2000).

Several other relationships for QoL, which are well established in the literature, were replicated in the current study. The first of these was that both diabetes specific and generic QoL were reduced as the number of complications increased. This is a particularly robust relationship that has been reported in numerous studies (see for example de Visser *et al.,* 2002; Brown *et al.,* 2000; UKPDS study group, 1999). Participants taking tablets and insulin also had significantly worse QoL than those just taking oral hypoglycaemic medication, which is consistent with previous studies (Katon *et al.,* 2004; Redekop *et al.,* 2002). In addition reduced QoL was associated with higher depression, anxiety and negative affect, which is consistent with studies by Brown *et al.,* (2000); Goldney *et al.,* (2004) and Claiborne & Massaro, (2000).

A relatively common finding in both the diabetes and general population literature is that female gender is associated with reduced QoL (Hirsh *et al.,* 2000; Glasgow *et al.,* 1997), although some studies with a UK population have reported that QoL is not significantly different between genders (Woodcock *et al.,* 2001). In the current study gender differences were found on the SF-36 PCS but not for diabetes specific QoL or the SF-36 MCS. It is not clear why this distinction was seen only on the PCS. Females also

reported higher negative affect than males in the current study, which is consistent with previous research (Katon *et al.,* 2004). It is surprising however that females did not report higher levels of depression than males as this is an established relationship in the literature (Nichols *et al.,* 2003; Katon *et al.,* 2004), however the small number of females and the low levels of depression in the current study may in part explain this.

The current study is consistent with previous research in many ways however some findings that may have been expected were not present. In particular the lack of association between glycaemic control and either behaviour, QoL or psychological well-being measures was unexpected. Previous studies have reported glycaemic control to be associated with self-management behaviours (Duncan *et al.,* 2003; Boule *et al.,* 2001; Karter *et al.,* 2001), QoL (see Rubin & Peyrot, 1999) and depression (Lustman *et al.,* 2000). The reason for lack of association at baseline in the current study is unclear.

At baseline there was also no relationship between self-management behaviours and either QoL or psychological well-being, with the exception of exercise and positive affect. There is relatively little previous research on this topic however and findings have been inconsistent. The results of this study would suggest that following a regimen is not associated with particular burden. This is in contrast to what has been suggested in some previous studies (Watkins *et al.,* 2000)

Social support was also not associated with self-management behaviours, a relationship that has previously been reported (Connell *et al.,* 1992; Wang & Fenske, 1996; William & Bond, 2002). It is important however that only a general social support measure was used at this stage of the analysis given the poor reliability of the DFBC-II. Both Connell *et al.,* (1992) and Wilson, Ary, Biglan, Glasgow & Toobert, (1986) reported that specific

social support scales are better predictors of behaviour than general scales, which may explain the current findings.

CHAPTER EIGHT - EFFICACY OF THE UCL-DSMP

8.1 Structure of the Chapter

This chapter reports on the efficacy of the UCL-DSMP. It begins by describing attrition from the programme and characteristics of programme drop-outs. The effect on outcome and process measures at each follow-up assessment (immediately post-intervention (IPI), 3 month follow-up (3mths) and 9 month follow-up (9mths) is then reported. ANCOVAs were performed for each outcome followed by post-hoc analysis using Bonferroni adjustments to examine changes within groups from baseline to follow-up. Tables are presented of data comparing differences between groups and within group from baseline. Statistically significant results are highlighted in bold and displayed in graphs. Graphs show mean scores at baseline and follow-up for ease of interpretation. The chapter concludes with consideration given to the maintenance of changes over time. Repeated measure ANOVAs were conducted for this analysis. Only individuals who completed all four assessments are included in this analysis.

At each follow-up some participants did not complete assessments and are described as 'lost to follow-up'. It should be noted that this is different from attrition to the programme, as participants included in loss to follow-up may have continued in the research project but just missed one or two of the assessments, for example data missing for IPI but available for baseline, 3 and 9 month follow-ups. Loss to follow-up is reported at the beginning of the appropriate sections.

8.2 Attrition from the UCL-DSMP

Participants were defined as programme dropouts if they completed less than 4 of the 6 sessions, including the booster session. In total 8 of the 65 participants allocated to the

intervention group did not complete the required number of sessions. The reasons given for this included going on holiday, caring for a sick spouse, participant sickness and work commitments. In addition two participants who were allocated to the intervention group and completed baseline assessments did not attend any sessions, one due to work commitments and the other to personal difficulties. Overall, programme attrition was calculated at 15% (n=10). Comparison of programme completers and dropouts revealed significant differences between participants on one baseline characteristic. This was HbA1c level, which was significantly higher at baseline for those who dropped out relative to those who completed the self-management programme (9.8 vs 8.3, t= -2.67 $p<0.01$).

Further analysis of the self-management programme did not include drop-outs as the primary focus was on intervention efficacy. Intention to treat analysis which addresses intervention effectiveness has been performed however and reported in the scientific literature (see appendix 6).

8.3 Efficacy of the UCL-DSMP at Immediate Post Intervention

8.3.1 Loss to Follow –up at Immediate Post Intervention

Of the sample to be analysed (n=124), 6 participants (5%) (4 waiting list control, 2 intervention group) were lost to follow-up at IPI. At baseline these individuals differed from those who completed assessments only on belief about diabetes seriousness, such that those individuals lost to follow-up had a slightly higher belief in the seriousness of diabetes than those who were assessed (3.33 vs 3.00, t= 2.77, $p<0.05$).

Analysis at IPI was therefore performed on a sample of 108 participants (55 control group, 53 intervention group).

Table 8.1 The Impact of the Self-Management Programme on Self-Management Behaviours at Immediate Post-Intervention

	Baseline Mean ± sd	IPI Mean ± sd	Post-hoc analysis of within group change from baseline	Between group differences ANCOVA F-Statistic
Diet General – Int	4.92±1.92	5.75±1.22	**F(1,df =106) =13.62 (P<0.001)**	**F(1,df =105) = 13.12**
Con	5.07±2.21	4.93±2.01	F(1,df = 106) = .43 (p=0.51)	**P<0.001**
Diet Fruit – Int	4.15±2.82	5.02±2.43	**F(1,df = 106) = 4.65 (p<0.05)**	**F(1,df= 105)=13.35**
Con	4.22±2.99	3.44±3.00	**F(1,df = 106) = 5.53 (p<0.05)**	**P<0.001**
Diet Fat – Int	4.66±2.24	5.49±1.72	**F(1,df = 106) = 8.96 (p<0.01)**	**F(1,df =105)=5.55**
Con	5.09±1.81	4.95±1.59	F(1,df = 106) = 0.28 (p=0.59)	**P<0.05**
Exercise – Int	2.25±2.24	3.95±2.09	**F(1,df = 106) = 36.74 (p<0.01)**	**F(1,df = 105)=12.68**
Con	2.85±2.29	3.05±2.38	F(1,df = 106) = 0.48 (p=0.49)	**P<0.001**
SMBG – Int	3.38±3.09	5.08±1.97	**F(1,df =106) = 22.69 (p<0.001)**	**F(1,df =105)=21.25**
Con	2.73±2.76	2.95±2.82	F(1,df = 106) = 0.39 (p=0.53)	**P<0.001**
% Stopped Smoking				$\chi^2 = 1.71$
Int		12.5%		ns
Con		15.4%		

Int – Intervention Group, Con – Control Group; revised SDSCA Scale (n=55 Int, n=53 Con); p values for post-hoc analysis are Bonferroni adjusted.

8.3.2 Impact on Behaviour at IPI

8.3.2.1 Diet – In ANCOVAs for general dietary behaviour, consumption of fruit and vegetables and avoidance of a high fat diet the intervention group showed significant improvements following the SMI compared to the control group (see table 8.1 & figures 8.1-8.3). All dietary behaviours were increased from baseline to IPI in the intervention group. The control group showed no change from baseline in general dietary behaviours or avoidance of a high fat diet but significantly decreased the frequency with which they consumed fruit and vegetables.

Figure 8.1 Change in General Diet at IPI

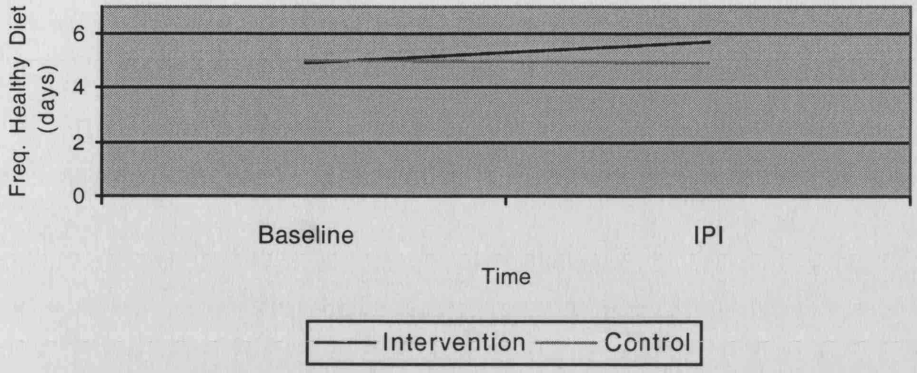


Figure 8.2 Change in Fruit & Veg. at IPI

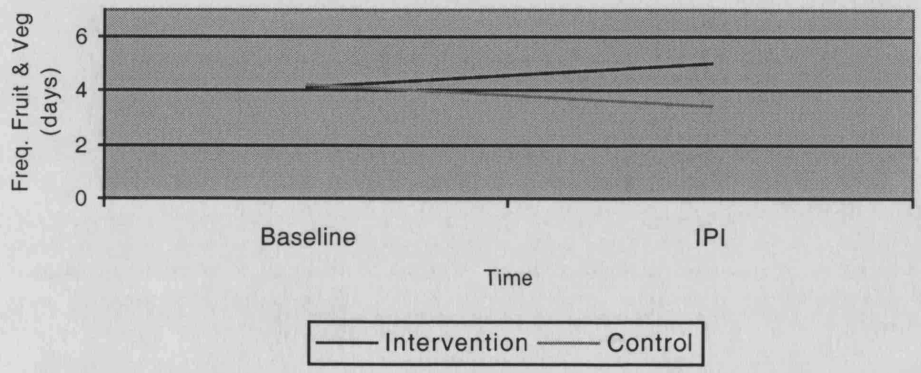
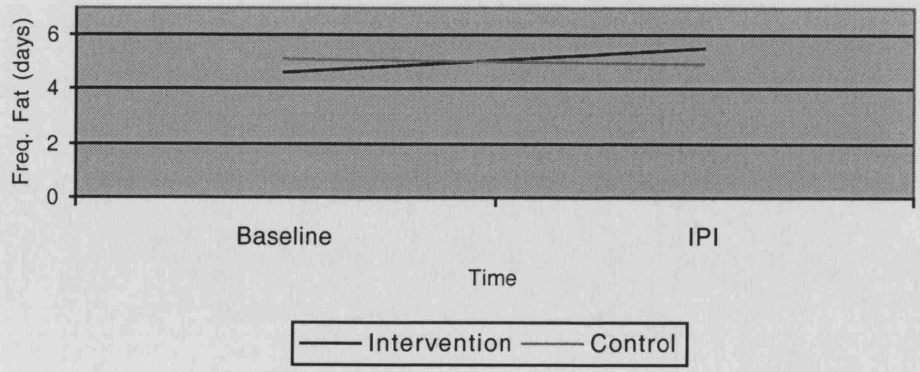
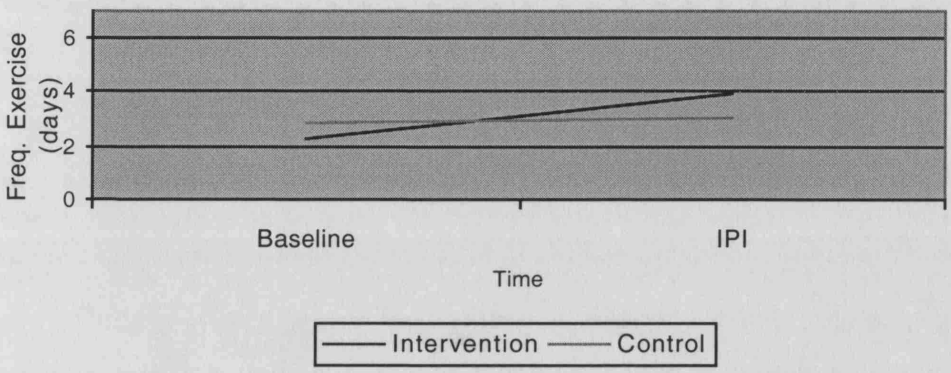


Figure 8.3 Change in Fat Consumption at IPI



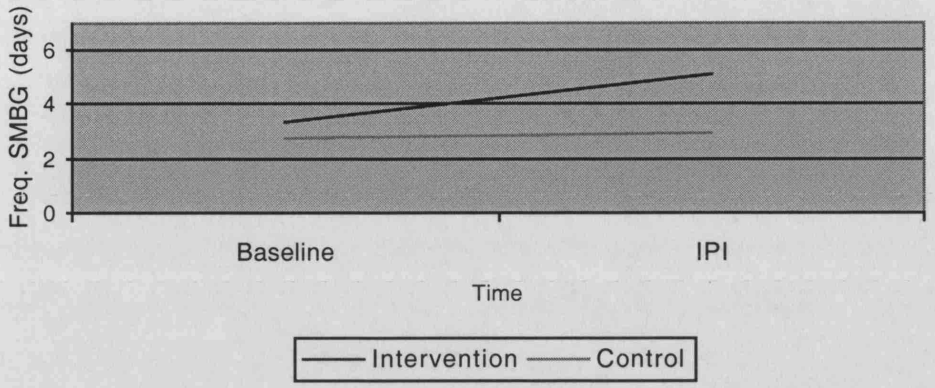
8.3.2.2 Exercise – At IPI the intervention group exercised significantly more frequently than the control group (see table 8.1, figure 8.4). The level of exercise in the intervention group was significantly more frequent at IPI than at baseline ($p<0.001$). This was in comparison to the control group who showed no change in the frequency of exercise.

Figure 8.4 Change in Exercise at IPI



8.3.2.3 Self Monitoring of Blood Glucose - The frequency with which SMBG was performed was significantly greater in the intervention group than the control group at IPI ($F(1,df=105) = 21.25$ $p<0.001$), see figure 8.5. The differences between the groups was attributable to a significant increase in the frequency with which the intervention group tested their blood sugars between baseline and IPI ($p<0.001$) while no change in frequency was reported for the control group.

Figure 8.5 Change in SMBG at IPI



8.3.2.4 Smoking - Of the seven individuals in the intervention group who were smokers at baseline one individual had given up at IPI (12.5%). One individual in the intervention group who reported not smoking at baseline had recommenced smoking at IPI. In the control group, of thirteen individuals who smoked at baseline two had given up at IPI (15. 4%). The proportions of individuals giving up smoking did not differ between the groups at post-intervention (χ^2 (1,21)= 1.71, p>0.05).

8.3.3 Impact on Quality of Life at IPI

Diabetes specific QoL as measured by the ADDQoL was significantly better for the intervention group at IPI as compared to the control group (F(1,df=105)=6.68 p<0.05) (see table 8.2 and figure 8.6). The direction of change was for the intervention group to show significant improvement in QoL over time (p<0.05) while the control group reported deterioration, although the latter was not significant.

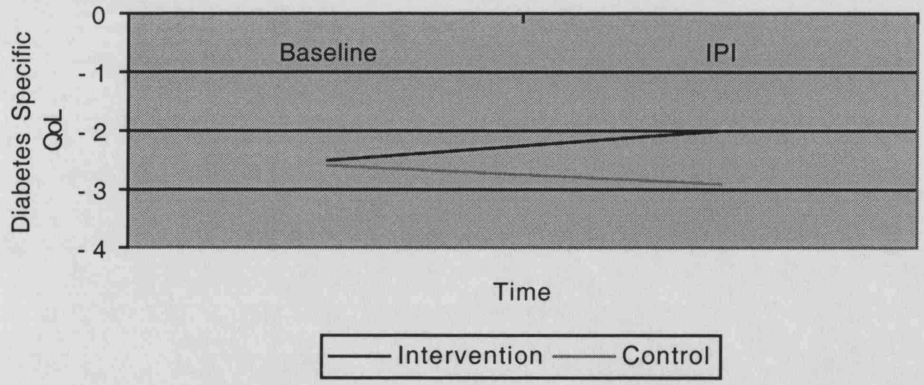
Table 8.2 The Impact of the Self-Management Programme on Quality of Life at Immediate Post-Intervention

	Baseline Mean ± sd	**IPI Mean ± sd**	**Post-hoc analysis of within group change from baseline**	**Between group differences ANCOVA F-Statistic**
ADDQoL - Int	-2.49±2.08	-2.02±2.18	**F(1, df=106) = 4.05 p<0.05**	**F(1,df=105) = 6.68 P<0.05**
Con	-2.61±1.98	-2.93±2.35	F(1,df =106) = 1.98 p=0.16	
SF-36 PCS Int	38.09±13.17	35.51±13.14	**F(1, df=104) = 4.39 p<0.05**	F(1,df =103) = 1.29 p=0.23
Con	38.25±12.83	37.47±12.87	F(1, df =104) = 0.43 p=0.51	
SF-36 MCS Int	50.52±8.40	52.29±10.66	F(1,df =103) = 2.46 p=0.12	F(1,df =102) = 0.33, p=0.57
Con	53.13±8.54	53.14±7.67	F(1,df =103) = 0.00 p=0.99	

Int – Intervention Group, Con – Control Group; PCS – physical composite score, MCS – mental composite score. ADDQoL (n= 55 SMI, n= 53 Con) SF-36 (n = 55 Int, 51 Con); p values for post-hoc analysis are Bonferroni adjusted.

There were no significant differences between groups at IPI on the generic measure of QoL. The intervention group did however show a significant deterioration from baseline on the SF-36 PCS compared to baseline. The control group did not show any change in this measure from baseline. Neither group varied from baseline on the SF-36 MCS.

Figure 8.6 Change in ADDQoL at IPI



8.3.4 Impact on Psychological Well-Being at IPI

Assessment of both positive and negative affect and anxiety and depression at IPI indicated that there were no significant differences between the groups (see table 8.3). There were also no changes within either group from baseline.

Table 8.3 The Impact of the Self-Management Programme on Psychological Well-Being at Immediate Post-Intervention

	Baseline Mean ± sd	**IPI Mean ± sd**	**Post-hoc analysis of within group change from baseline**	**Between group differences ANCOVA F-Statistic**
Positive Affect – Int	13.24±4.94	12.80±4.70	F(1, df= 96) = 0.43 p=0.51	F(1,df = 95) =0.35 P=0.56
Con	13.19±5.77	13.23±4.93	F(1,df = 96) = 0.00 p=0.95	
Negative Affect– Int	8.54±3.94	7.98±3.97	F(1,df = 96) = 1.15, p=0.29	F(1,df = 95) =0.39, p=0.53
Con	7.98±2.87	7.35±2.71	F(1,df =96) = 1.64 , p=0.20	
Depression- Int	3.25±2.79	3.39±3.26	F(1,df = 96) = 0.18 p=0.68	F(1,df = 95) = 1.24, P=0.27
Con	3.19±2.56	2.89±2.17	F(1,df = 96) = 1.02 p=0.32	
Anxiety- Int	5.16±3.71	5.14±4.10	F(1,df = 96) = 0.00 p=0.96	F(1,df = 95) = 0.84, P=0.36
Con	4.59±3.19	4.22±3.27	F(1,df=96)= 0.99, p=0.32	

Int – Intervention Group, Con – Control Group; PANAS (n=52 Int, n=46 Con), HAD Scale (n=54 Int, n=44 Con); p values for post-hoc analysis are Bonferroni adjusted

8.3.5 Impact on Process Variables at IPI

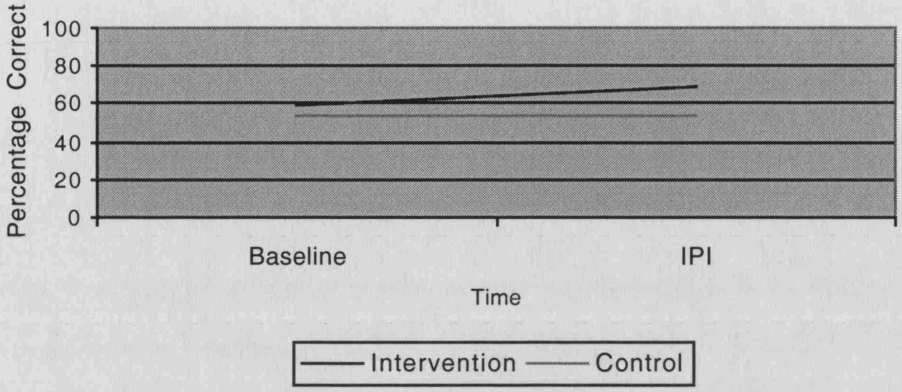
8.3.5.1 Knowledge – This variable showed a clear benefit of the self-management programme with individuals in the intervention group having significantly higher knowledge levels at IPI than control group participants $F(1,df=100) = 19.52$, $p<0.001$) (see table 8.4, figure 8.7). This difference was attributable to an increase in knowledge levels from baseline to IPI for the intervention group ($p<0.001$), while there was no change over time for the control group.

Table 8.4 The Impact of the Self-Management Programme on Process Variables at Immediate Post-Intervention

		Baseline Mean ± sd	**IPI Mean ± sd**	**Post-hoc analysis of within group change from baseline**	**Between group differences ANCOVA F-Statistic**
Knowledge-	Int	58.63±19.77	69.34±18.87	**F(1,df=101) = 23.49, p<0.001**	**F(1,df=100) = 19.52P<0.001**
	Con	53.38±19.96	54.03±18.22	F(1,df = 101) = 0.09, p=0.75	
Self-Efficacy					
Total –	Int	69.52±16.99	72.01±14.22	F(1,df = 100) = 1.95, p=0.17	F(1,df =99)=1.30 P=0.26
	Con	68.99±19.45	69.21±18.17	F(1,df = 100) = 0.02, p=0.89	
Diet -	Int	68.78±22.56	70.61±18.86	F(1,df = 102) = 0.39, p=0.53	F(1,df =101)=0.05 P=0.82
	Con	67.55±26.21	69.27±21.93	F(1,df = 102) = 0.39, p=0.54	
SMBG-	Int	84.62±24.26	87.44±16.18	F(1,df = 82) = 0.56, p=0.46	F(1,df =81)=1.61 P=0.21
	Con	81.44±22.70	80.56±26.23	F(1,df = 82) = 0.06, p=0.80	
Exercise-	Int	60.83±30.62	67.08±28.00	F(1,df = 100) = 3.18, p=0.08	F(1,df = 99)=1.62 P=0.21
	Con	60.93±32.49	62.04±26.05	F(1,df = 100) = 0.11, p=0.74	
Personal Models					
Seriousness	Int	3.06±0.87	3.11±0.77	F(1,df = 105) = 0.28 p=0.59	F(1,df =104)=0.64 P=0.43
	Con	2.93±0.92	2.93±0.92	F(1,df = 105) = 0.00, p=1.00	
Treat. Eff.	Int	3.84±0.57	4.10±0.45	**F(1,df=105) = 13.53, p<0.001**	**F(1,df= 104)=11.08 P<0.001**
	Con	3.78±0.62	3.81±0.52	F(1,df =105) = 0.16, p=0.69	
Control	Int	3.25±0.87	3.64±0.76	**F(1,df = 105) = 9.42, p<0.01**	**F(1,df =104)=3.75 P=0.05**
	Con	3.20±0.96	3.33±0.95	F(1,df = 105) = 1.03, p=0.31	
Readiness to Change					
Diet	Int	6.21±0.91	6.02± 1.52	F(1,df = 100) = 1.04, p=0.31	F(1,df= 99) = 1.96, p=0.16
	Con	6.27± 1.01	6.36 ±0.82	F(1,df = 100) = 0.27 p=0.66	
SMBG	Int	6.15±1.12	6.26±1.21	F(1,df = 100) = 0.32, p=0.58	F(1,df= 99) = 0.27, p=0.87
	Con	6.11±1.40	6.27±1.31	F(1,df = 100) = 0.88 p=0.35	
Exercise	Int	5.87±1.39	5.83±1.40	F(1,df = 100) = 0.04, p=0.84	F(1,df= 99) = 0.12, p=0.73
	Con	5.82±1.55	5.89±1.44	F(1,df = 100) = 0.14 p=0.71	
Medication	Int	5.89± 1.67	6.15±1.20	F(1,df = 100) = 1.05, p=0.31	F(1,df= 99) = 0.33, p=0.86
	Con	5.45±1.94	5.93±1.71	**F(1,df = 100) = 4.20 p=0.04**	

Int – Intervention Group, Con – Control Group, Knowledge (n=55 Int, n=48 Con), Self-Efficacy (n=55 Int, n=47 Con) Personal Models (n=54 Int, 53 Con), Readiness to Change (n=47 Int, n=55 Con); p values for post-hoc analysis are Bonferroni adjusted

Figure 8.7 Change in Knowledge at IPI



8.3.5.2 Self-Efficacy - Self-efficacy did not differ significantly between the groups either when the composite scale was considered or when individual scores for each behaviour were assessed. In addition neither control or intervention group reported change in self-efficacy over time.

8.3.5.3 Illness Cognitions – No differences between groups were found for belief in the seriousness of diabetes. When scores for belief in treatment effectiveness and control over blood glucose were considered, significant differences between the groups were observed ($F(1,df=104)=11.08$ $p<0.001$) and ($F(1,df=104)=3.75$ $p=0.05$) respectively – see figures 8.8 & 8.9). The intervention group reported significant increases in both of these beliefs from baseline, whilst the control group showed no change on either measure.

Figure 8.8 Change in Treatment Effectiveness at IPI

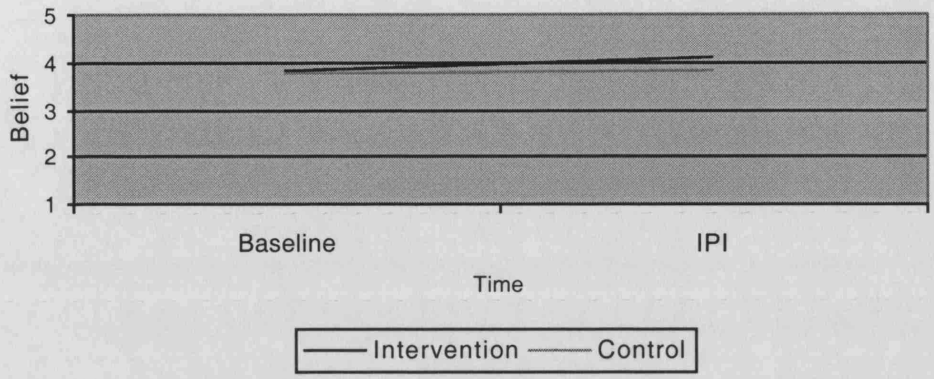
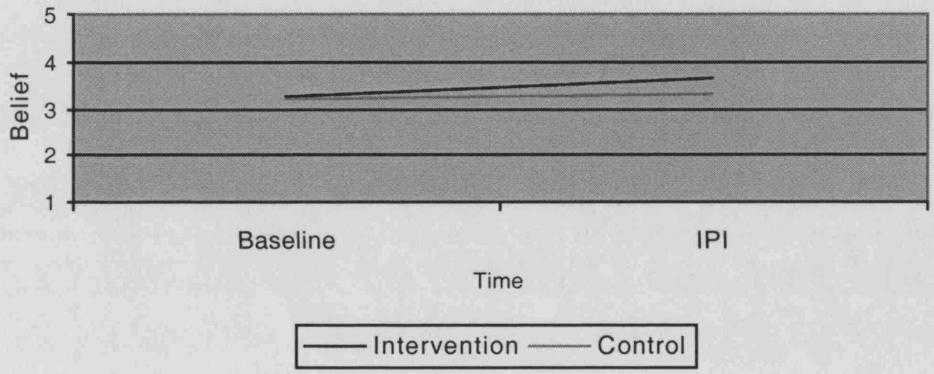


Figure 8.9 Change in Beliefs in Control at IPI



8.3.5.4 Readiness to Change- No significant differences between groups were observed following the intervention. The control group did however increase their RTC medication behaviours from baseline. No other differences between baseline and IPI were observed between groups.

8.4 Efficacy of the UCL-DSMP at 3 Months Follow-Up

8.4.1 Loss to Follow-Up at 3 Months

Thirteen participants (11%) (8 control group, 5 intervention group), did not complete assessments at 3 months follow-up. Three of these individuals had not completed assessments at IPI while the other ten had. The only difference on baseline characteristics between those lost to follow-up and assessment completers at 3 months was on the frequency of fruit and vegetable consumption. Individuals who were lost to follow-up had significantly lower fruit and vegetable consumption at baseline (2.08 vs 4.34 $t=-2.17$ $p<0.01$). Analysis at 3 months follow-up was performed on 101 participants (50 waiting list control, 51 intervention group). However as at IPI some measures, particularly those assessing psychological well-being or process variables, were not completed by all participants, variations in n are indicated as appropriate.

8.4.2 Impact on Glycaemic Control at 3 Months Follow-Up

ANCOVA with baseline HbA1c levels used as a covariate indicated that there was no significant difference between intervention and control groups at 3 months follow-up (see table 8.5). Analysis within groups indicated that for the intervention group HbA1c levels improved significantly ($p<0.05$) from baseline to 3 month follow-up, while the control group did not change significantly during this period.

Table 8.5 The Impact of the Self-Management Programme on Glycaemic Control at 3 Months Follow-Up

		Baseline Mean ± sd	**3 Months Mean ± sd**	**Post-hoc analysis of within group change from baseline**	**Between group differences ANCOVA F-Statistic**
HbA1c–	Int	8.18±1.31	7.87± 1.12	**F(1,df = 97) = 3.93,p=0.05**	F(1, df = 96)=2.52
	Con	8.65±1.84	8.50±1.69	F(1,df = 97)=1.03, p=0.31	P=0.11

Int – Intervention Group, Con – Control Group, HbA1c (n=46 Int, n=53 Con); p values for post-hoc analysis are Bonferroni adjusted

8.4.3 Impact on Behaviours at 3 Months Follow-Up

Table 8.6 shows the impact of the intervention on self-management behaviours.

8.4.3.1 Diet - At 3 months follow-up control and intervention groups did not differ significantly on general dietary behaviour, ($F(1,df=98) = 1.28$, $p>0.05$). Neither did the groups differ significantly on the specific diet items of fruit and vegetable consumption ($F(1, df=98) = 1.54$, $p>0.05$). There was however a trend towards significance for avoidance of high fat foods ($F(1,df=98) = 3.58$, $p=0.06$).

Post-hoc analysis to compare within group differences from baseline to 3 months indicated that within the intervention group there was a significant improvement in both general dietary behaviour and avoidance of high fat foods ($p<0.01$). There was no change on these variables in the control group. For fruit and vegetable consumption there was no significant change between baseline and 3 months follow-up for either the control or intervention group.

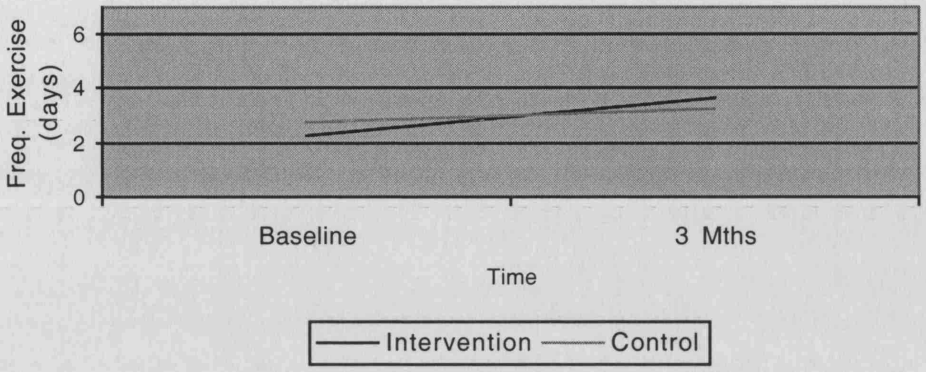
Table 8.6 The Impact of the Self-Management Programme on Self-Management Behaviours at 3 Months Follow-Up

		Baseline Mean ± sd	3 Months Mean ± sd	Post-hoc analysis of within group change from baseline	Between group differences ANCOVA F-Statistic
Diet General–	Int	4.87±1.89	5.54± 1.21	**F(1,df=99) = 7.91,p<0.01**	F(1,df=98)=1.29
	Con	5.08±2.14	5.35±1.70	F(1,df=99) = 1.35,p=0.25	P=0.26
Diet Fruit –	Int	4..06±2.83	4.66±2.52	F(1,df=99) = 2.32, p=0.13	F(1,df=98)=1.54
	Con	4.61±2.88	4.33±2.77	F(1,df=99) = 0.49,p=0.48	P=0.22
Diet Fat –	Int	4.58±2.27	5.38±1.68	**F(1,df=99) = 7.08,p<0.01**	F(1,df=98)=3.58
	Con	5.10±1.71	4.92±1.89	F(1,df=99) = 0.35,p=0.56	P=0.06
Exercise –	Int	2.22±2.23	3.60±2.27	**F(1,df=99) = 24.70,p<0.001**	**F(1,df=98)=4.34**
	Con	2.79±2.18	3.21±2.07	F(1,df=99) = 2.24,p=0.14	**P<0.05**
SMBG–	Int	3.34±3.03	4.54±2.29	**F(1,df=99) = 9.68,p<0.01**	**F(1,df=98)=6.18**
	Con	2.69±2.69	3.16±2.73	F(1,df=99) = 1.52,p=0.22	**P<0.05**
% stopped smoking			12.5% (n=1of8) 10.0%(n=1of10)		χ^2 (2,df=18)=2.96 ns

Int – Intervention Group, Con – Control Group; SDSCA Scale (n=51 Int, n=50 Con); p values for post-hoc analysis are Bonferroni adjusted.

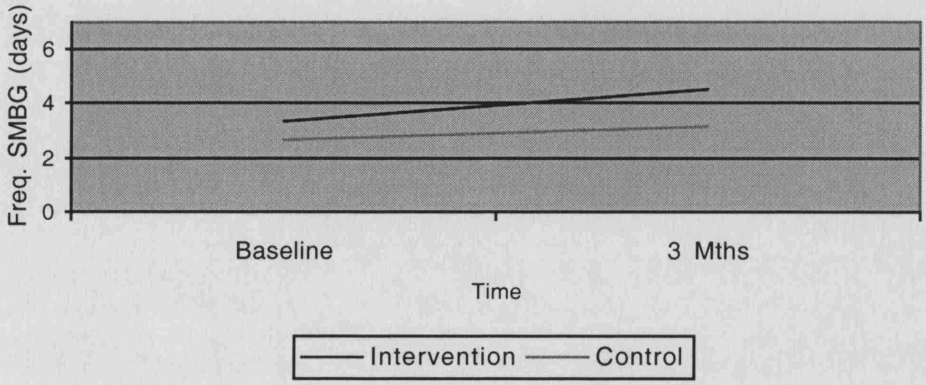
8.4.3.2 Exercise – The frequency of exercise behaviour in the intervention group was significantly different from the control group at 3 months follow-up ($F(1,df=98) = 4.34$, $p<0.05$) (see figure 8.10). Examination of group means indicated that the intervention group engaged in exercise more frequently than the control group at this assessment period. Comparison of exercise over time showed that those in the intervention group significantly improved from baseline ($p<0.001$) while the control group showed no significant changes between baseline and 3 months follow-up.

Figure 8.10 Change in Exercise at 3 Months



8.4.3.3 Self- Monitoring of *Blood Glucose* – ANCOVAs showed that the intervention group and control group differed on SMBG at 3 months follow-up ($F(1,df=98) = 6.18$ $p<0.05$, see graph 8.11). The intervention group tested their blood sugars significantly more frequently than the control group. Within group analysis indicated that the control group did not improve significantly between baseline and 3 months, while the intervention group increased the frequency with which they tested blood glucoses as compared to baseline ($p<0.01$).

Figure 8.11 Change in SMBG at 3 Months



8.4.3.4 Smoking – At three months follow-up one individual in the intervention group had given up smoking since baseline (12.5%) although two original non-smokers had started/ re-started smoking. In the control group only ten of the original thirteen smokers completed the assessment and of these one (10%) had given up smoking. There was no difference between the groups in the proportion of original smokers who had given up (χ^2 (2,df=18)=2.96, Yates correction applied).

8.4.4 Impact on Quality of Life at 3 Months Follow-Up

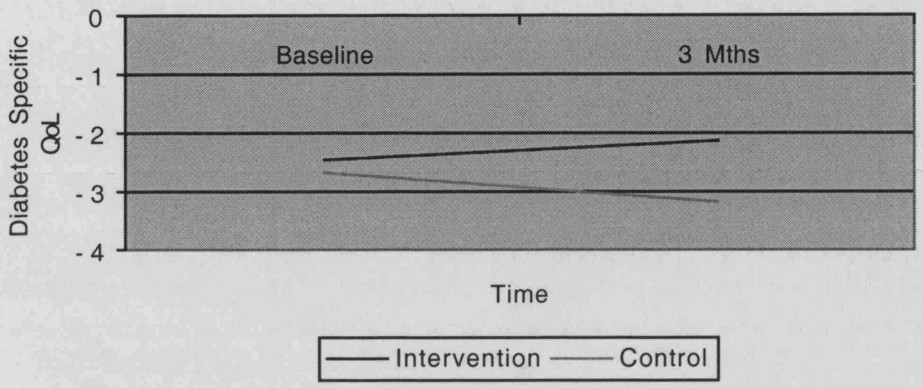
Diabetes specific QoL was significantly different between groups at 3 months follow-up (F(1,98) = 8.85, p<0.01) with the intervention group reporting significantly better QoL than the control group (see table 8.7, figure 8.12). Comparison over time indicated that this difference between groups was due to a significant deterioration in the control group from baseline (p<0.05). The intervention group improved from baseline although this was not significant.

Table 8.7 The Impact of the Self-Management Programme on Quality of Life at 3 Months Follow-Up

		Baseline Mean ± sd	**3 Months Mean ± sd**	**Post-hoc analysis of within group change from baseline**	**Between group differences ANCOVA F-Statistic**
ADDQoL	Int	-2.47±2.06	-2.15±1.97	F(1,df=99) = 2.20, p=0.14	**F(1,df=98) =8.85, P<0.01**
	Con	-2.66±1.98	-3.17±2.32	**F(1,df=99) = 5.61, p<0.05**	
SF-36 PCS	Int	38.03±12.98	37.41±14.26	F(1,df=99)=0.22, p=0.64	F(1,df=98) = 0.88, p=0.35
	Con	38.55±12.85	36.14±14.24	F(1,df=99)=3.39 p=0.07	
SF-36 MCS	Int	51.23±8.31	52.95±9.61	F(1,df=99)=1.53, p=0.22	F(1,df=98) =1.15, p=0.28
	Con	52.82±8.46	51.86±10.65	F(1,df=99)=0.48 p=0.49	

Int – Intervention Group, Con – Control Group; ADDQoL (n=51 Int, n=50 Con), SF-36 (n=50 Int, n=51 Con); p values for post-hoc analysis are Bonferroni adjusted

Figure 8.12 Change in ADDQoL at 3 Months



At 3 months follow-up there were no differences between groups on either the SF-36 PCS or SF-36 MCS. Neither control nor intervention groups showed change from baseline on either of these outcomes.

Table 8.8 The Impact of the Self-Management Programme on Psychological Well-Being at 3 Months Follow-Up

	Baseline Mean ± sd	**3 Months Mean ± sd**	**Post-hoc analysis of within group change from baseline**	**Between group differences ANCOVA F-Statistic**
Positive Affect – Int	13.16±5.15	14.00±3.96	F(1,df=90)=1.67, p=0.19	F(1,df=89)=1.61, p=0.21
Con	13.29±5.71	13.19±4.49	F(1,df=90)=0.03, p=0.87	
Negative Affect– Int	8.34±4.01	8.81±4.15	F(1,df=90)=0.69, p=0.41	F(1,df=89)=0.01, p=0.92
Con	8.00±2.92	8.54±4.08	F(1,df=90)=0.97, p=0.33	
Depression- Int	3.11±2.78	3.18±2.74	F(1,df=90)=0.04, p=0.85	F(1,df=89)=0.16, p=0.69
Con	3.26±2.61	3.10±2.95	F(1,df=90)=0.23, p=0.63	
Anxiety- Int	4.93±3.66	4.86±3.59	F(1,df=90)=0.02, p=0.88	F(1,df=89)=0.02, p=0.89
Con	4.86±3.27	4.90±3.69	F(1,df=96)= 0.01, p=0.93	

Int – Intervention Group, Con – Control Group; PANAS (n=48 Int, n=44 Con), HAD Scale (n= 50 Int, n=44 Con); p values for post-hoc analysis are Bonferroni adjusted

8.4.5 Impact on Psychological Well-Being at 3 Months Follow-Up

None of the measures of psychological well-being, including depression, anxiety, positive affect or negative affect showed significant differences between intervention and control groups at 3 months follow-up when controlling for baseline scores (see table 8.8). In addition there were no significant changes from baseline levels for any of these variables when within group analysis was performed at 3 months follow-up.

8.4.6 Impact on Process Variables at 3 Months Follow-Up

8.4.6.1 Knowledge – ANCOVA at 3 months follow-up for knowledge (n= 98) demonstrated a significant group effect ($F(1,95) = 24.1$, $p<0.001$), such that individuals attending the self-management programme had higher scores at follow-up than the control group did (see table 8.9, figure 8.13). Post-hoc analysis of change within group showed that the intervention group had significantly increased knowledge scores from baseline ($p<0.001$) while the control group did not change significantly over time.

Figure 8.13 Change in Knowledge at 3 Months

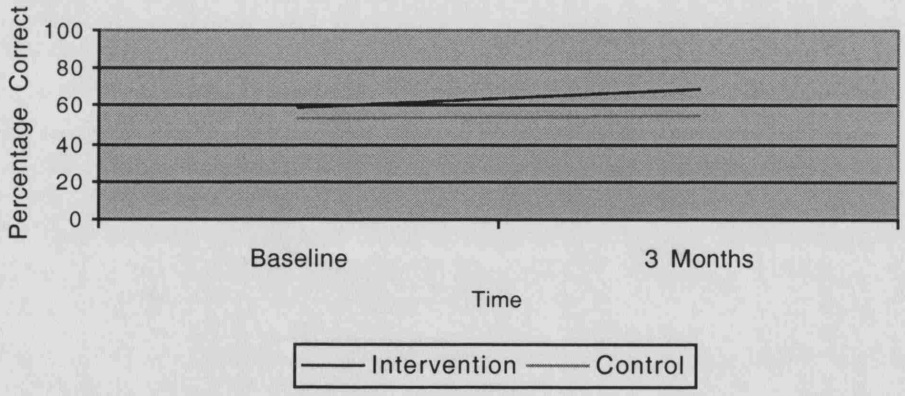


Table 8.9 The Impact of the Self-Management Programme on Process Variables at 3 Months Follow-Up

		Baseline Mean ± sd	3 Months Mean ± sd	Post-hoc analysis of within group change from baseline	Between group differences ANCOVA F-Statistic
Knowledge	Int	58.81±17.48	69.60±17.34	**F(1,df=96)=32.61,p<0.001**	**F(1,df=95)=24.12,**
	Con	53.22±20.32	54.62±17.49	F(1,df=96)=0.60, p=0.44	**P<0.001**
Self-Efficacy					
Total	Int	70.13±15.93	72.93±14.80	F(1,df=95)=2.54,p=0.11	F(1,df=94)=2.27,
	Con	70.03±19.39	69.73±16.08	F(1,df=95)=0.03, p=0.85	P=0.14
Diet	Int	70.00±21.62	73.09±17.80	F(1,df=96)=1.69,p=0.19	F(1,df=95)=1.45,
	Con	68.82±25.27	69.22±19.93	F(1,df=96)=0.03, p=0.86	P=0.23
SMBG	Int	84.36±24.15	87.05±16.45	F(1,df=96)=0.47,p=0.49	**F(1,df=79)=4.07,**
	Con	79.88±23.34	76.63±24.95	F(1,df=96)= 0.76,p=0.39	**P<0.05**
Exercise	Int	60.64±30.92	69.49±24.68	**F(1,df=96)=8.68,p<0.01**	**F(1,df=94)=5.59**
	Con	61.40±33.11	62.00±26.61	F(1,df=96)=0.04, p=0.84	**P<0.05**
Personal Models					
Seriousness	Int	3.06±0.89	3.11±0.81	F(1,df=99)=0.36,p=0.55	F(1,df=98)=0.92,
	Con	3.01±0.90	2.96±0.96	F(1,df=99)=0.27, p=0.60	P=0.34
Treat Eff	Int	3.90±0.48	4.06±0.49	**F(1,df=99)=5.79,p<0.05**	F(1,df=98)=3.26,
	Con	3.80±0.63	3.82±0.71	F(1,df=99)=0.09, p=0.76	P=0.07
Control	Int	3.28±0.86	3.60±0.64	**F(1,df=99)=5.83,p<0.05**	F(1,df=98)=2.99,
	Con	3.18±0.93	3.31±0.91	F(1,df=99)=1.09, p=0.30	P=0.09
Readiness to Change					
Diet	Int	6.14±1.09	6.41±0.82	**F(1,df=94)=4.39,p<0.05**	**F(1,df=93)=3.76,**
	Con	6.35±0.97	6.23±1.04	F(1,df=94)=0.93, p=0.34	**P=0.05**
SMBG	Int	6.09± 1.14	6.55±0.76	**F(1,df=94)=5.71,p<0.05**	F(1,df=93)=2.81,
	Con	6.19±1.31	6.25±1.22	F(1,df=94)=0.11, p=0.74	P=0.09
Exercise	Int	5.80±1.41	5.64±1.46	F(1,df=94)=0.52, p=0.47	F(1,df=93)=0.26,
	Con	5.77±1.60	5.75±1.31	F(1,df=94)=0.01, p=0.93	P=0.62
Medication	Int	5.80±1.69	6.23±1.27	F(1,df=94)=3.14, p=0.08	F(1,df=93)=0.07,
	Con	5.52±1.96	6.04±1.64	**F(1,df=94)=5.36, p=0.02**	P=0.79

Int – Intervention Group, Con – Control Group, Knowledge (n=47 Int, n=51 Con), Self-Efficacy (n=51 Int, n=46 Con) Personal Models (n=51 Int, 50 Con), Readiness to Change (n=44 Int, n=52 Con); p values for post-hoc analysis are Bonferroni adjusted

8.4.6.2 Self-Efficacy - For the composite measure of self-efficacy there was no difference between groups at 3 months follow-up. However, when the self-efficacy items for individual behaviours (i.e. diet, exercise and SMBG) were examined separately it was apparent that there was a group effect for exercise ($F(1,94) = 5.59$, $p<0.05$) (see figure 8.14) and SMBG ($F(1,79) = 4.07$, $p<0.05$) (see figure 8.15), but not for diet. The group effects indicated that the intervention group had significantly greater self-efficacy than the control group for both SMBG and exercise behaviour at 3 months follow-up when controlling for baseline. Subsequent analysis considering change from baseline indicated that the intervention group had significantly greater confidence in performing exercise behaviour at 3 months than they did at baseline ($p<0.01$). The control group did not show significant change between assessments. There were also no significant changes in self-efficacy scores from baseline for either the control or intervention group for diet self-efficacy, SMBG self-efficacy or the composite self-efficacy scale at 3 months follow-up.

Figure 8.14 Change in Exercise Self-Efficacy at 3 Months

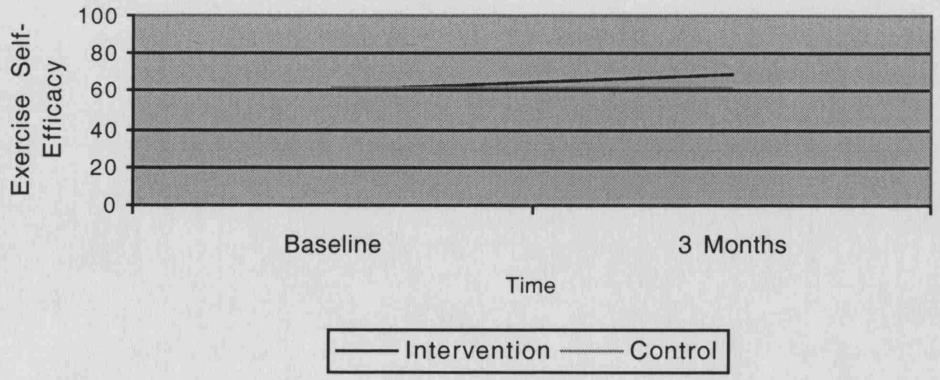
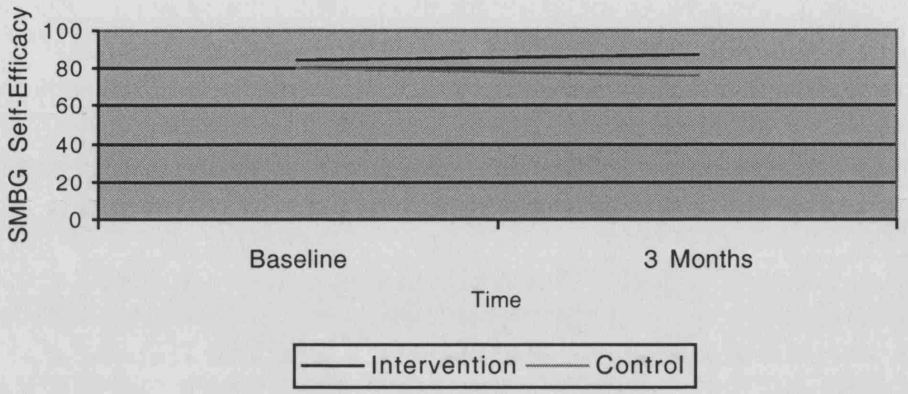


Figure 8.15 Change in SMBG Self-Efficacy at 3 Months



8.4.6.3 Illness Cognitions - Comparison of participant's personal models about diabetes at 3 months follow-up when controlling for baseline scores indicated that there was no significant difference between groups for any of the three components of seriousness, treatment effectiveness or sense of control (see table 8.9). Treatment effectiveness did however indicate a non-significant trend ($F(1,98) = 3.26$, $p=0.07$) towards a difference between groups at 3 months follow-up. Examination of personal models in within group analysis, over time, showed that the intervention group significantly increased their beliefs in treatment effectiveness ($p<0.05$) and sense of control over blood glucose ($p<0.05$) from baseline to 3 months follow-up, while the control group demonstrated no significant changes during this time period on any of the personal models sub-scales.

8.4.6.4 Readiness to Change - ANCOVAs indicated that there was a significant difference between groups on RTC dietary behaviour at 3 months follow-up. The intervention group reported greater RTC diet than the control group ($F(1,93)=3.76$, $P=0.05$). The intervention group had significantly increased their RTC dietary behaviour

from baseline ($p<0.05$) whilst there was no significant change from baseline for the control group. There were no significant differences between groups for RTC other self-management behaviours at 3 month follow-up. The intervention group did however significantly increase their RTC SMBG between baseline and 3 months ($p<0.05$) and the control group significantly increased their RTC medications ($p<0.05$). No other changes from baseline were observed for either group.

8.5 Efficacy of Standard Self-Management Programme at 9 Months Follow-Up

8.5.1 Loss to Follow-Up at 9 months

Twelve (11%) (7 control group, 5 intervention group) participants did not complete assessments at 9 months follow-up. Comparison of individuals lost to follow-up at this time-point and study completers indicated those missing from analysis were significantly younger (53.33 vs 60.64 $t=-2.81$ $p<0.05$) and had higher knowledge levels (67.26 versus 59.34 $t=2.00$ $p<0.05$) at baseline. In total a maximum of 102 participants (52 waiting list control, 50 intervention group) were evaluated at this time point. As reported at previous follow-ups, for some variables, not all participants completed evaluations. The 'n' on each variable is indicated as appropriate.

8.5.2 Impact on Glycaemic Control at 9 Months Follow-Up

ANCOVA of HbA1c at 9 months follow-up indicated no significant differences between groups ($F(1,df=100) = 0.27$ $p>0.05$) (see table 8.10). In addition examination of post-hoc analysis indicated that neither the intervention group nor control group showed significantly different scores from baseline.

Table 8.10 The Impact of the Self-Management Programme on Glycaemic Control at 9 Months Follow-Up

		Baseline Mean ± sd	9 Months Mean ± sd	Post-hoc analysis of within group change from baseline	Between group differences ANCOVA F-Statistic
HbA1c–	Int	8.27±.0.22	8.07± 0.21	F(1,df = 101) = 1.91,p=0.17	F(1,df =100)=0.27
	Con	8.66±0.21	8.42±0.19	F(1,df = 101)=1.22, p=0.27	P=0.60

Int – Intervention Group, Con – Control Group, HbA1c (n=46 Int, n=53 Con); p values for post-hoc analysis are Bonferroni adjusted

8.5.3 Impact on Behaviour at 9 Months Follow-Up

8.5.3.1 Diet – General dietary behaviour did not differ between intervention and control groups at 9 months follow-up (F(1,df=99) = 0.19, p>0.05) (see table 8.11), and neither group showed significantly different scores from baseline. For the specific dietary behaviours of fat and fruit consumption again there were no differences between groups or changes from baseline for either group at 9 months follow-up.

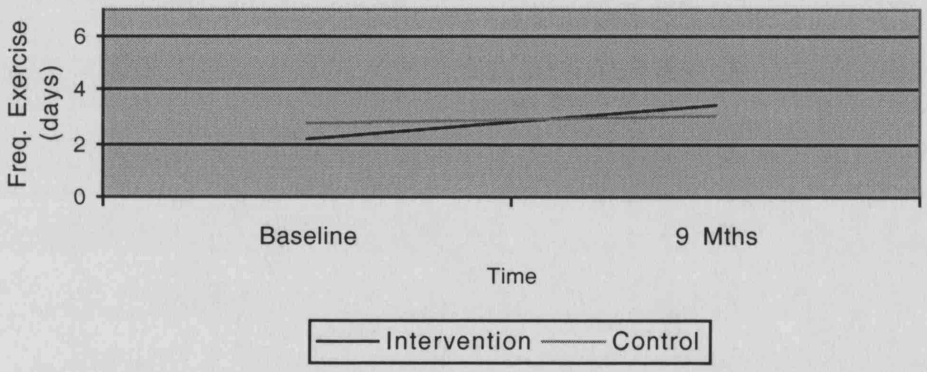
Table 8.11 The Impact of the Self-Management Programme on Behaviours at 9 Months Follow-Up

		Baseline Mean ± sd	9 Months Mean ± sd	Post-hoc analysis of within group change from baseline	Between group differences ANCOVA F-Statistic
Diet General–	Int	4.73±2.03	5.03±1.84	F(1,df=100)=0.96, p=0.33	F(1,df=99)=0.19,
	Con	5.13±2.14	5.30±1.64	F(1,df=100)=0.29, p=0.59	P=0.66
Diet Fruit -	Int	4.12±2.83	4.68±2.52	F(1,df=100)=1.76, p=0.19	F(1,9df=9)=2.83P=.10
	Con	4.31±2.95	3.92±3.05	F(1,df=100)=0.86, p=0.36	
Diet Fat –	Int	4.64±2.15	5.22±1.86	F(1,df=100)=2.95, p=0.09	F(1,df=99)=1.44
	Con	5.15±1.70	4.88±1.90	F(1,df=100)=0.66 p=0.42	P=0.23
Exercise –	Int	2.14±2.21	3.45±2.31	**F(1,df=100)=21.82, p<0.001**	**F(1,df=99)=5.28**
	Con	2.80±2.23	3.03±2.22	F(1,df=100)=0.70, p=0.40	**P<0.05**
SMBG –	Int	3.47±3.05	4.62±2.28	**F(1,df=100)=7.20, p=0.01**	**F(1,df=99)=4.47**
	Con	2.78±2.82	3.35±2.94	F(1,df=100)=1.82, p=0.18	**P<0.05**
% given up smoking			38% n=3/ 8 9.1% n=1/11		χ^2 (1,df=19)=2.25

Int – Intervention Group, Con – Control Group; SDSCA Scale (n=52 Int, n=50 Con); p values for post-hoc analysis are Bonferroni adjusted

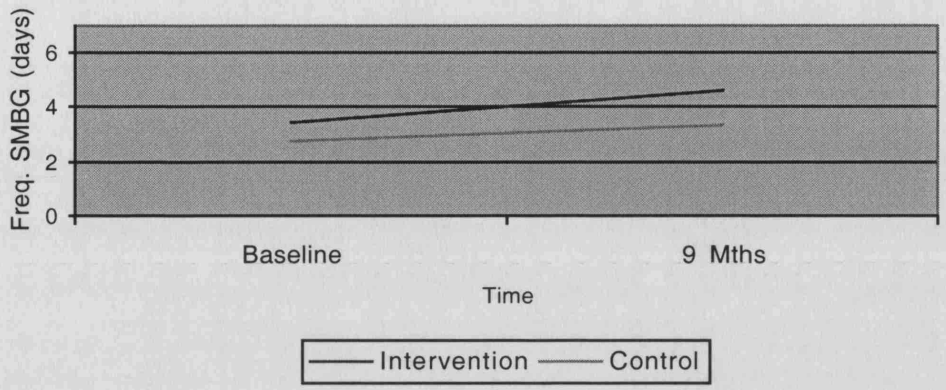
8.5.3.2 Exercise - The frequency of exercise behaviour was significantly influenced by the intervention at 9 months follow-up when baseline levels were controlled for ($F(1,df=99) = 5.28$ $p<0.05$). Individuals in the intervention group exercised significantly more frequently than the control group at 9 months follow-up (see figure 8.16). Post-hoc analysis indicated that the control group showed no change from baseline whilst the intervention group significantly increased the amount they exercised from baseline ($p<0.001$) (see table 8.11).

Figure 8.16 Change in Exercise at 9 Months



8.5.3.3 Self Monitoring of Blood Glucose – The effect of the intervention was significant for SMBG ($F(1,df=99) = 4.46$, $p<0.05$, see figure 8.17) at 9 months post-intervention, with the intervention group performing blood glucose tests significantly more frequently than the control group. Within group analysis however showed that although the pattern was for both groups to increase testing at 9 months as compared to baseline there was only a significant increase in the intervention group ($p<0.01$).

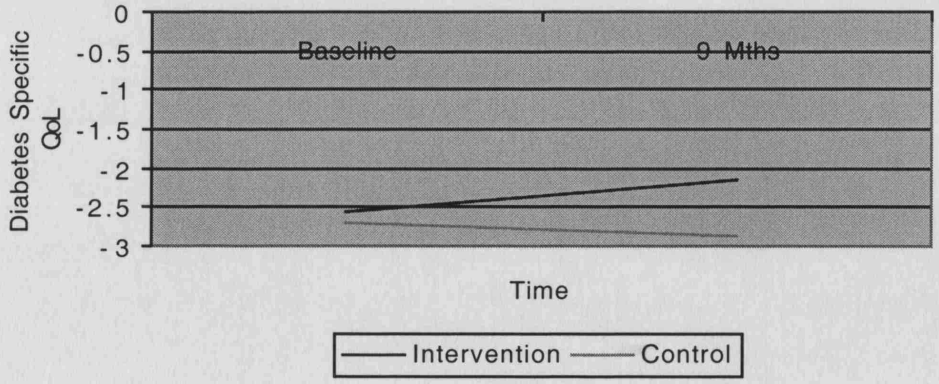
Figure 8.17 Change in SMBG at 9 Months



8.5.3.4 Smoking – At nine months follow-up three out of eight individuals (38%) in the intervention group who were classified as smokers at baseline had given up smoking. This was compared to one out of eleven (9%) in the control group. This difference was not significantly different (χ^2 (1,df=19)=2.25, Yates correction applied).

8.5.4 Impact on Quality of Life at 9 Months Follow-Up

Figure 8.18 Change in ADDQoL at 9 Mths



When controlling for baseline scores a significant intervention effect ($F(1,df=99) = 4.56$ $p<0.05$), was found for diabetes specific QoL at 9 months follow-up (see table 8.12, figure 8.18). Participants who attended the self-management programme reported better QoL than control group participants. Post-hoc analysis indicated that at 9 months follow-up neither group had significantly different scores from baseline, however whilst the direction of change for the intervention group was towards improved QoL it was towards poorer QoL for the control group.

Table 8.12 The Impact of the Self-Management Programme on Quality of Life at 9 Months Follow-Up

		Baseline Mean ± sd	**9 Months Mean ± sd**	**Post-hoc analysis of within group change from baseline**	**Between group differences ANCOVA F-Statistic**
ADDQoL	Int	-2.54±2.13	-2.16±1.61	F(1,df=100)=2.89, p=0.09	**F(1,df=99)=4.57 P<0.05**
	Con	-2.69±1.99	-2.85±2.17	F(1,df=100)=0.52, p=0.47	
SF-36 PCS	Int	36.92±12.9	35.03±14.24	F(1,df=99)=1.75, p=0.19	F(1,df=98)=38.25, p=0.52
	Con	38.16±12.9	37.22±13.41	F(1,df=99)=0.46, p=0.49	
SF-36 MCS	Int	50.57±1.23	51.89±1.44	F(1,df=99)=0.96, p=0.33	F(1,df=98)=3.46, p=0.07
	Con	52.98±1.19	50.03±1.40	**F(1,df=99)=5.12, p=0.03**	

Int – Intervention Group, Con – Control Group; ADDQoL (n=52 Int, n=50 Con), SF-36 (n=49 Int, n=52 Con); p values for post-hoc analysis are Bonferroni adjusted

There were no significant differences between groups when controlling for baseline scores on either the SF-36 PCS or SF-36 MCS at 9 month follow-up, although there was a trend towards difference for the SF-36 MCS ($F(1,df=98)=3.46$, $p=0.07$). On this latter sub-scale the intervention group showed no change from baseline however the control group significantly deteriorated from baseline to 9 months follow-up. There were no significant changes over time for either group on the SF-36 PCS.

8.5.5 Impact on Psychological Well-Being at 9 Months Follow-Up

There was no significant intervention effect on any of the measures of psychological well-being (see table 8.13) when controlling for baseline scores. In addition post-hoc analysis did not demonstrate any significant differences within groups from baseline to 9 months follow-up for either the control or intervention group on any of the assessments of psychological well-being. A trend (p=0.07) towards increased negative affect between baseline and 9 months follow-up was however observed for the control group.

Table 8.13 The Impact of the Self-Management Programme on Psychological Well-Being at 9 Months Follow-Up

	Baseline Mean ± sd	**9 Months Mean ± sd**	**Post-hoc analysis of within group change from baseline**	**Between group differences ANCOVA F-Statistic**
Positive Affect – Int	12.89±5.11	12.96±4.40	F(1,df=99)=0.01, p=0.92	F(1,df=91)=0.20
Con	12.92±5.73	13.31±4.51	F(1,df=99)=0.36, p=0.55	P=0.65
Negative Affect– Int	8.24±3.55	8.29±3.86	F(1,df=99)=0.01, p=0.95	F(1,df=91)=1.39
Con	8.08±2.91	9.20±5.26	F(1,df=99)=3.32, p=0.07	P=0.24
Depression- Int	3.09±2.72	3.19±2.92	F(1,df=99)=0.07, p=0.80	F(1,df=90)=0.67
Con	3.20±2.57	3.66±3.19	F(1,df=99)=1.91, p=0.17	P=0.42
Anxiety- Int	4.95±3.73	4.88±3.86	F(1,df=99)=0.02, p=0.88	F(1,df=90)=0.02
Con	4.66±3.28	4.58±3.90	F(1,df=99)=0.04, p=0.85	P=0.89

Int – Intervention Group, Con – Control Group; PANAS (n=49 Int, n=45 Con), HAD Scale (n= 50 Int, n=43 Con); p values for post-hoc analysis are Bonferroni adjusted

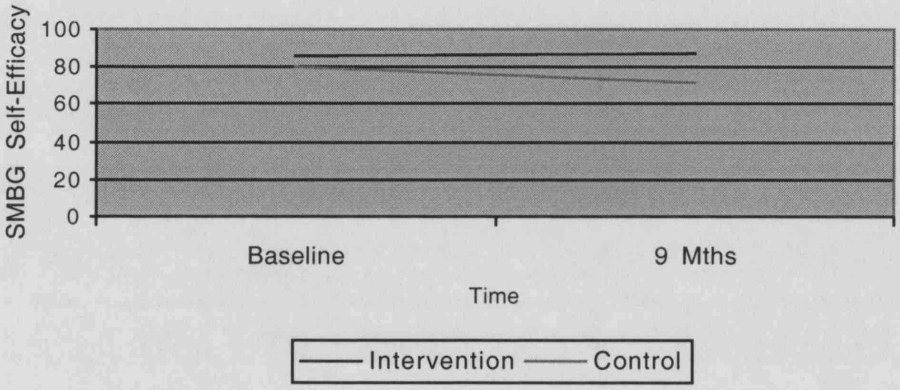
8.5.6 Impact on Process Variables at 9 Months Follow-Up

Knowledge and RTC were not assessed at 9 months follow-up, therefore effects of the intervention on these variables at 9 months is not reported.

8.5.6.1 Self-Efficacy - The total self-efficacy score and self-efficacy scores for diet and exercise behaviour did not show an effect of the intervention at 9 months when controlling for baseline scores (see table 8.14). Post-hoc analysis of the diet, exercise

and total self-efficacy scores indicated neither the control or intervention group had significant changes from baseline to 9 months. When controlling for baseline scores SMBG self-efficacy showed an intervention effect ($F(1,df=77) = 6.91$, $p<0.01$), such that participants in the intervention group had higher self-efficacy than the control group at 9 months follow-up (see figure 8.19). Post-hoc analysis indicated that between baseline and 9 months follow-up the control group showed significant deterioration ($p<0.05$) in SMBG self-efficacy while the intervention group showed no significant change.

Figure 8.19 Change in SMBG Self-Efficacy at 9 Months



8.5.6.2 Illness Cognitions - There were no significant differences between the groups on any subscale of personal models of diabetes at 9 months follow-up (see table 8.14). In addition changes from baseline were not significant for either group on any sub-scale. There was however a trend ($p=0.054$) for increased belief in treatment effectiveness in the intervention group between baseline and 9 months follow-up.

Table 8.14 The Impact of the Self-Management Programme on Process Variable at 9 Months Follow-Up

		Baseline Mean ± sd	9 Months Mean ± sd	Post-hoc analysis of within group change from baseline	Between group differences ANCOVA F-Statistic
Self-Efficacy					
Total	Int	68.51±17.05	69.18±17.04	F(1,94)=0.07, p=0.79	F(1,93)=0.09
	Con	69.54±19.50	68.81±18.53	F(1,94)=0.09, p=0.76	P=0.76
Diet	Int	67.72±22.53	68.20±22.92	F(1,96)=0.02, p=0.88	F(1,95)=0.71
	Con	68.56±25.17	71.71±19.99	F(1,96)=1.04, p=0.31	P=0.40
SMBG	Int	85.28±24.20	88.00±15.92	F(1,78)=0.29, p=0.59	**F(1,77)=6.91**
	Con	80.80±23.45	71.48±32.52	**F(1,78)=4.12, p<0.05**	**P<0.01**
Exercise	Int	58.75±31.92	62.18±29.69	F(1,94)=0.57, p=0.45	F(1,93)=0.65
	Con	60.96±33.06	59.02±32.35	F(1,94)=0.21, p=0.65	P=0.42
Personal Models					
Seriousness	Int	3.08±0.88	2.93±0.85	F(1,100)=1.75, p=0.19	F(1,99)=0.29
	Con	2.95±0.91	2.93±0.91	F(1,100)=0.03 p=0.87	P=0.59
Treat Eff	Int	3.82±0.58	3.95±0.61	**F(1,100)=3.81, p=0.05**	F(1,99)=0.29
	Con	3.78±0.60	3.87±0.54	F(1,100)=2.28, p=0.13	P=0.59
Control	Int	3.22±0.89	3.48±0.74	F(1,100)=2.96, p=0.09	F(1,99)=0.12
	Con	3.21±0.96	3.42±0.91	F(1,100)=2.04 p=0.16	P=0.73

Int – Intervention Group, Con – Control Group, Self-Efficacy (n=52 Int, n=44 Con) Personal Models (n=52 Int, 50 Con); p values for post-hoc analysis are Bonferroni adjusted

8.6 Maintenance of Changes over Follow-Up Assessments

Maintenance of intervention effects was explored by repeated measures ANOVA with post-hoc analysis of within group changes over time. This analysis required participants to have completed measures at all four assessment times i.e. baseline, IPI, 3 months and 9 months (For HbA1c ANOVA was conducted on baseline, 3 months and 9 months assessments and for RTC and knowledge ANOVAs were conducted on baseline, IPI and 3 month assessments only as data was not available at other time points). Ninety three participants completed all four assessment periods (49 control group, 44 intervention group). This is obviously less than when assessment periods were analysed separately as reported above.

8.6.1 Maintenance of Changes in Glycaemic Control

On repeated measure ANOVA there were no significant changes in HbA1c between any assessment period for either control or intervention groups.

Table 8.15 Glycaemic Control at Each Assessment

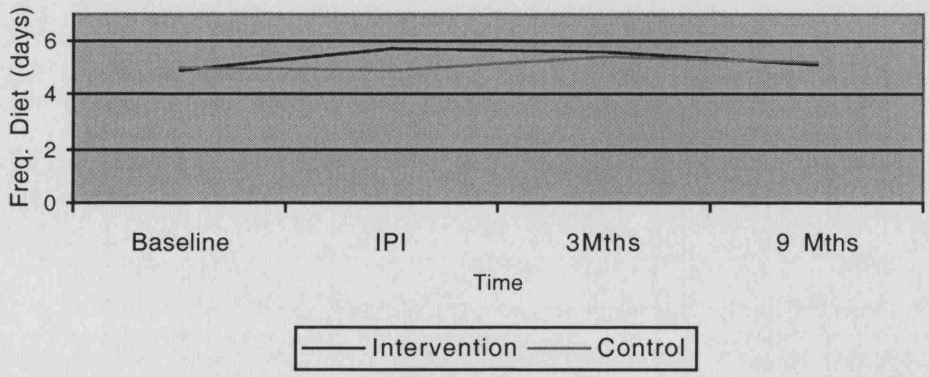
		Baseline Mean ± sd	IPI Mean ± sd	3 Months Mean ± sd	9 Months Mean ± sd	Interaction Effect F Statistic
HbA1c	Int	8.28±1.23	-	7.96±1.08	8.01±1.18	F(1,df=89)=0.34,
	Con	8.56±1.70	-	8.40±1.44	8.36±1.64	p=0.71

Int – Intervention Group, Con – Control Group; HbA1c (n=50 Int, n=42). [a] significant difference from baseline ($p<0.05$), [b] significant difference from IPI ($p<0.05$), [c] significant difference from 3 mths ($p<0.05$), [d] significant difference from 9 months. [e] significant difference between groups ($p<0.05$); p values for post-hoc analysis are Bonferroni adjusted.

8.6.2 Maintenance of Changes in Behaviour

8.6.2.1 Diet – An improvement was found in the intervention group in general dietary behaviour between baseline and IPI. Levels of general dietary behaviour did not deteriorate significantly between IPI and 3 or 9 months follow-ups in the intervention group and there was no significant change between 3 and 9 months post-intervention (see table 8.16, figure 8.20).

Figure 8.20 Change in General Diet Over All Assessments



The directional change for general dietary behaviour in the intervention group was however towards baseline levels. The control group did not have significantly different scores to baseline on any follow-up. At three and nine month follow-ups this group did have higher scores for general dietary behaviour than at baseline.

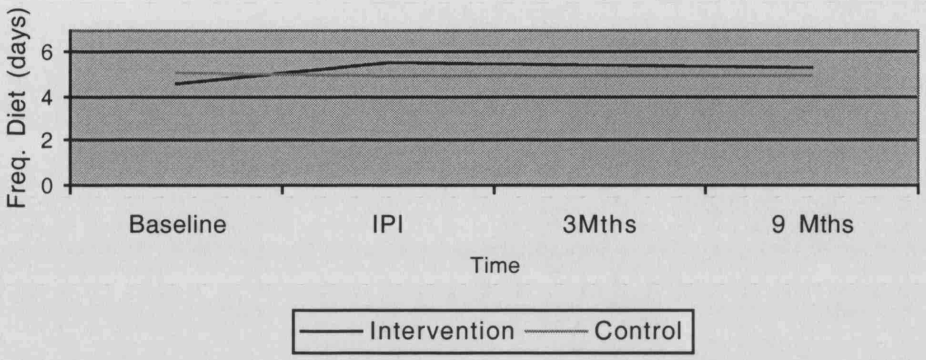
Table 8.16 Self-Management Behaviours at Each Assessment

		Baseline Mean ± sd	IPI Mean ± sd	3 Months Mean ± sd	9 Months Mean ± sd	Interaction Effect F Statistic
Diet General–	Int	4.92±1.81	5.76±1.11[a, e]	5.59±1.24[a]	5.11±1.75	F(1,df=89) = 3.47,
	Con	5.07±2.19	4.93±1.95	5.38±1.74	5.22±1.66	p<0.05
Diet Fruit-	Int	4.32±2.82	5.14±2.38[e]	4.89±2.49	4.80±2.49	F(1,df=89) = 3.18,
	Con	4.51±2.90	3.61±2.99	4.31±2.82	4.08±3.03	p<0.05
Diet Fat-	Int	4.61±2.27	5.52±1.80[a]	5.39±1.71	5.34±1.78	F(1,df=89) = 2.06,
	Con	5.12±1.74	5.00±1.40	4.96±1.91	4.89±1.88	p=0.11
Exercise-	Int	2.28±2.20	3.70±2.05[a]	3.65±2.33[a]	3.67±2.27[a]	F(1,df=89) = 3.61
	Con	2.77±2.21	3.04±2.42	3.24±2.10	3.02±2.28	P<0.05
SMBG –	Int	3.60±3.11	4.90±2.02[a,e]	4.55±2.39[e]	4.56±2.34[e]	F(1,df=89) = 1.64,
	Con	2.66±2.75	2.92±2.83	3.12±2.78	3.23±2.89	P=0.19

Int – Intervention Group, Con – Control Group; SDSCA Scale (n=52 Int, n=50 Con) [a] significant difference from baseline (p<0.05), [b] significant difference from IPI (p<0.05), [c] significant difference from 3 mths (p<0.05), [d] significant difference from 9 months. [e] significant difference between groups (p<0.05); p values for post-hoc analysis are Bonferroni adjusted

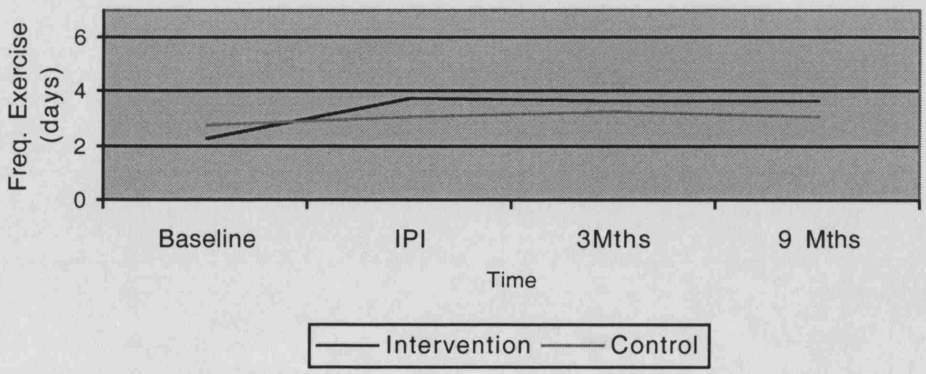
For fruit and vegetable consumption neither the intervention or control group showed significant changes from baseline at any follow-up assessment, however the pattern was for the intervention group to have greater consumption of fruit and vegetables compared to baseline whilst the control group had lower consumption than at baseline. The same pattern was seen for avoidance of a high fat diet, with the intervention group following a low fat diet more frequently at follow-up assessments as compared to baseline whilst the converse was true for the control group. Only at IPI in the intervention group however was the change from baseline significant (see table 8.16, figure 8.21).

Figure 8.21 Change in Fat Consumption Over All Assessments



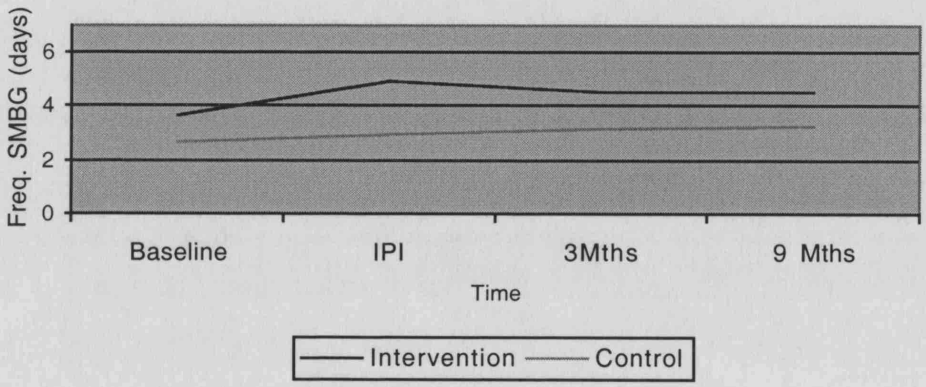
8.6.2.2 Exercise – The intervention group exercised significantly more frequently than at baseline at all follow-up assessments (see table 8.16, figure 8.22). The frequency of exercise behaviour did not change significantly between IPI, 3 months and 9 months follow-ups in the intervention group, suggesting that the improvement from baseline was retained but not increased. In contrast the control group did not demonstrate any significant changes between follow-up assessments, and scores were not significantly different from baseline levels at any point.

Figure 8.22 Change in Exercise Over All Assessments



8.6.2.3 Self-Monitoring of Blood Glucose. The intervention group tested blood glucose significantly more frequently at IPI, 3 months & 9 months than at baseline (see table 8.16, figure 8.23). Changes in SMBG between IPI and 3 or 9 months follow-up did not however show significant change. In addition no changes were seen in frequency of SMBG between 3 months and 9 months follow-up, indicating that initial improvements in this behaviour were maintained over time. The control group did not show any change between baseline and follow-up assessments, and no changes were found between any of the follow-up assessments.

Figure 8.23 Change in SMBG Over All Assessments



8.6.3 Maintenance of Changes in Quality of Life

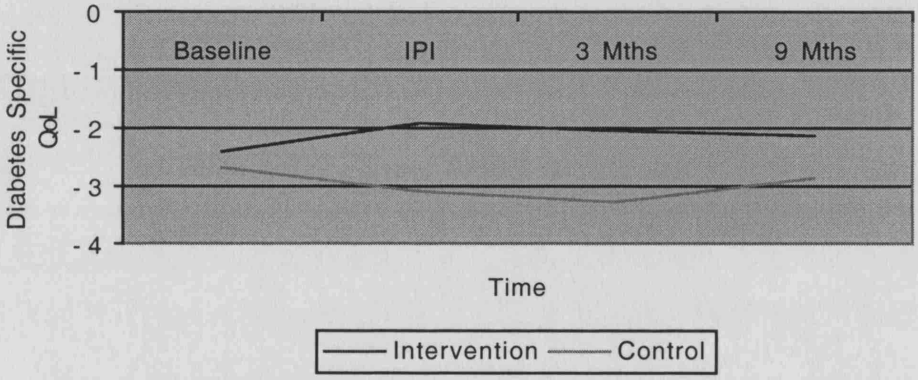
On repeated measures ANOVA the direction of change for diabetes specific QoL was towards improved QoL for the intervention group and towards decreased QoL for the control group. There were however no significant differences across any of the assessment periods for either of the groups (see table 8.17, figure 8.24).

Table 8.17 Quality of Life at Each Assessment

	Baseline Mean ± sd	IPI Mean ± sd	3 Months Mean ± sd	9 Months Mean ± sd	Interaction Effect F Statistic
ADDQoL Int	-2.40±2.12	-1.92±2.31 [e]	-2.03±1.92 [e]	-2.13±1.66	**F(1,df=89) = 3.25**
Con	-2.70±2.01	-3.07±2.40	-3.27±2.31	-2.88±2.17	**P<0.05**
SF-36 PCS Int	37.2±13.01	35.1±13.57	37.9±14.58	35.81±13.83	F(1,df=88) = 1.96,
Con	38.7±12.92	37.6±13.19	36.2±14.40	37.33±13.55	p=0.13
SF-36 MCS- Int	51.2±8.41	52.7±10.56	52.4±9.85	52.08±8.44	F(1,df=88) = 1.20,
Con	52.9±8.62	52.9±7.69	51.8±10.81	50.04±10.77	p=0.31

Int – Intervention Group, Con – Control Group; ADDQoL (n=49 Int, n=43 Con), SF36 (n=49 Int, n=43 Con) [a] significant difference from baseline (p<0.05), [b] significant difference from IPI (p<0.05), [c] significant difference from 3 mths (p<0.05), [d] significant difference from 9 months. [e] significant difference between groups (p<0.05); p values for post-hoc analysis are Bonferroni adjusted

Figure 8.24 Change in ADDQoL Over All Assessments



There was no change between baseline and any follow-up assessment for either the control or intervention group on the SF-36 PCS or SF-36 MCS. In addition there were no changes between follow-up assessments for either group on either SF-36 sub-scale.

8.6.4 Maintenance of Changes in Psychological Well-Being

None of the evaluations of psychological well-being including depression, anxiety, positive affect and negative affect showed significant changes between baseline and any

follow-up assessment for either control or intervention group. There were also no significant changes between any follow-up assessments for either the control or intervention group (see table 8.18).

Table 8.18 Psychological Well-Being at Each Assessment

	Baseline Mean ± sd	IPI Mean ± sd	3 Months Mean ± sd	9 Months Mean ± sd	Interaction Effect F Statistic
Positive Affect- Int	13.23±5.21	12.65±4.96	14.00±4.09	13.25±4.38	F(1,df= 82) = 0.96,
Con	13.15±5.77	13.07±4.86	13.13±4.58	13.61±4.48	p=0.42
Negative Affect- Int	8.20±3.69	7.95±4.16	8.93±4.24	8.35±4.01	F(1,82) = 0.67,
Con	7.98±2.89	7.54±2.80	8.57±4.12	9.26±5.39	p=0.57
Depression- Int	3.16±2.70	3.11±3.23	3.16±2.80	3.29±3.02	F(1,81) = 0.57,
Con	3.23±2.61	3.00±2.14	3.06±2.88	3.77±3.26	p=0.64
Anxiety- Int	5.13±3.74	5.03±4.21	5.05±3.67	5.00±3.98	F(1,81)= 0.21,
Con	4.79±3.34	4.36±3.35	4.81±3.71	4.65±4.00	p=0.89

Int – Intervention Group, Con – Control Group; PANAS (n=46 Int, n=40 Con), HAD Scale (n=47 Int, n=38 Con) [a] significant difference from baseline ($p<0.05$), [b] significant difference from IPI ($p<0.05$), [c] significant difference from 3 mths ($p<0.05$), [d] significant difference from 9 months. [e] significant difference between groups ($p<0.05$); p values for post-hoc analysis are Bonferroni adjusted

8.6.5 Maintenance of Changes in Process variables

8.6.5.1 Knowledge – Knowledge improved in the intervention group compared to baseline at IPI and was retained at 3 months follow-up (see table 8.19 and figure 8.25).

Figure 8.25 Change in Knowledge Over All Assessments

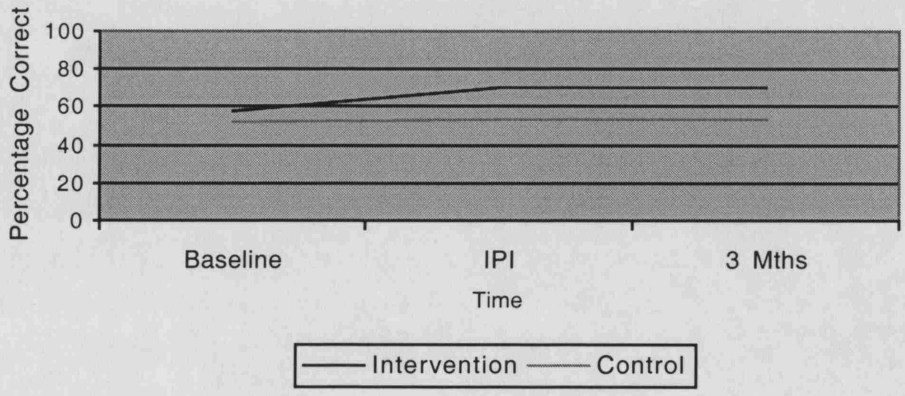


Table 8.19 Process Variables at Each Assessment

	Baseline Mean ± sd	IPI Mean ± sd	3 Months Mean ± sd	9 Months Mean ± sd	Interaction Effect F Statistic
Knowledge- Int	58.41±19.81	70.31±17.82[a,e]	69.84±16.60[a,e]	-	**F(1,df=92) = 8.63,**
Con	52.43±19.71	52.86±18.20	54.00±17.08	-	**p<0.001**
Self-Efficacy					
Total- Int	69.36±16.38	71.00±13.19	72.55±15.30	69.90±17.02	F(1,df=85) = 0.66,
Con	70.21±19.75	69.68±18.54	69.74±16.40	68.41±18.74	p = 0.58
Diet- Int	69.39±22.17	70.24±18.37	72.32±18.24	69.07±23.58	F(1,df=86) = 0.85,
Con	68.57±25.74	69.49±21.97	68.98±20.28	71.61±20.37	p=0.47
SMBG- Int	85.46±25.56	87.58±16.59	87.42±16.87[e]	89.03±16.19[e]	F(1,df=67) = 1.27,
Con	80.39±24.09	80.66±26.33	76.18±25.61	71.71±31.99	p=0.29
Exercise- Int	61.13±31.47	65.00±28.22	69.88±25.33[a]	64.28±29.55	F(1,df=84) = 1.64,
Con	61.88±33.72	63.23±26.65	61.88±27.14	58.73±32.30	p=0.19
Personal Models					
Seriousness- Int	3.04±0.93	3.11±0.75	3.12±0.80	2.92±0.88	F(1,df=88) = 1.31,
Con	2.99±0.92	2.99±0.90	2.93±0.97	2.97±0.91	p=0.28
Treat Eff- Int	3.89±0.51	4.13±0.40[a,e]	4.03±0.47[e]	4.04±0.49	F(1,df=88) = 1.56,
Con	3.76±0.61	3.83±0.52	3.79±0.71	3.88±0.56	p=0.21
Control- Int	3.27±0.14	3.68±0.13[a]	3.59±0.12[e]	3.52±0.13	F(1,df=88) = 1.01,
Con	3.21±0.13	3.38±0.13	3.25±0.11	3.40±0.12	p=0.39
RTC					
Diet- Int	6.23±0.90	6.02±1.57	6.44±0.80	-	**F(1,df=89) = 3.92,**
Con	6.37±0.93	6.43±0.74	6.22±1.05	-	**p<0.05**
SMBG- Int	6.09±1.15	6.26±1.24	6.27±1.20	-	F(1,df=89) = 1.17,
Con	6.16±1.34	6.35±1.22	6.53±0.77	-	p=0.32
Exercise- Int	5.88±1.29	5.81±1.44	5.72±1.37	-	F(1,df=89) = 0.16,
Con	5.80±1.63	5.90±1.49	5.73±1.34	-	p=0.86
Medication- Int	5.79±1.71	6.14±1.23	6.21±1.28	-	F(1,df=89) = 0.03,
Con	5.55±1.88	5.98±1.69	6.04±1.66	-	p=0.97

Int – Intervention Group, Con – Control Group; MDRTC Knowledge (n=50 Int, n=45 Con), Self-Efficacy (n=49 Int, n=40 Con), RTC (n=43 Int, n=49 Con) [a] significantly different from baseline ($p<0.05$), [b] significantly different from Immediate post intervention ($p<0.05$), [c] significantly different from 3 month follow-up ($p<0.05$), [d] significantly different from 9 months follow-up. [e] significant difference between groups ($p<0.05$); p values for post-hoc analysis are Bonferroni adjusted

Assessments of knowledge were not completed at 9 months follow-up, therefore it is not clear whether the improvements in the intervention group from baseline were retained in

the longer term. No significant changes in knowledge were observed in the control group from baseline or between IPI and 3 month assessments.

8.6.5.2 Self-Efficacy – Total self-efficacy, diet self-efficacy and SMBG self-efficacy did not show significant differences between any assessment periods for either control or intervention groups (see table 8.19). Exercise self-efficacy was significantly improved from baseline to 3 months follow-up in the intervention group. There was no significant difference between scores at 3 months and 9 months follow-up suggesting that some of the improvement had been retained. The control group did not show differences between assessments at any period for exercise self-efficacy.

8.6.5.3 Illness Cognitions- There were no significant differences between any assessments for either group on belief in seriousness of diabetes or perceived control of blood glucose. The intervention group strengthened their belief in treatment effectiveness significantly from baseline to IPI and there was not a significant decline in these scores at 3 or 9 months follow-up. The control group did not show change in this belief at any assessment.

8.6.5.4 Readiness to Change – Neither the intervention or control group showed significantly different scores between baseline and any follow-up assessment, or between follow-up assessments for any of the sub-scales.

CHAPTER NINE: DISCUSSION OF EFFICACY OF THE UCL-DSMP

9.1 Structure of the Chapter

The current chapter discusses the impact of the UCL-DSMP as presented in chapter eight. It covers the following: the acceptability of the intervention; the reasons why the social support intervention had lower uptake than the standard SMI and the efficacy of the SMI for outcome and process variables, at both IPI and over time. The relationship of the findings in the current study compared to previous SMI studies is also discussed.

9.2 Acceptability of the UCL-DSMP

Intervention acceptability can be measured in a number of ways including uptake into a research study, preference for intervention, drop-out from the intervention and specific responses to direct questioning of acceptability by participants. In the current study uptake, preference for the two interventions and intervention drop-outs were used as indicators of acceptability.

Although study uptake in part reflects an individual's willingness to take part in research in general, the type of intervention being studied is also likely to be an integral part of any decision to participate. If an intervention is not acceptable to the individual it is unlikely that they would agree to a process of randomisation where exposure to the intervention is possible. Overall participation rates for the current study have been discussed previously in chapter seven where it was reported that rates were comparable to similar studies. In addition the reasons given for refusal to participate were similar to those reported in other studies. This suggests that the current research study was no less acceptable to participants than in similar SMI studies.

The current study however, used a patient preference design. This enabled the differential acceptability of the two SMIs to be explored, as individuals expressed preference for attending either alone, and receiving the standard SMI, or with a partner and receiving the social support intervention. The marked lack of uptake into the social support intervention (over a 6 month period only 3 individuals were recruited into the social support intervention, in contrast to 23 into the standard SMI) suggests that this form of the programme was not acceptable to participants.

Two possible reasons can be advanced to account for why individuals chose not to participate in the social support intervention. Firstly 41% of participants in the study were either single, divorced or widowed, hence raising the issue of practicality of attending with a partner. Although the relationship of the person who attended the programme with the participant was not specified, it was emphasised that social support skills would be taught, so there should be a close relationship and frequent interaction between the two individuals. It is possible that for individuals who were single, divorced or widowed no such person was available. Even where a support individual was available it is clearly more difficult for two individuals to commit to the time requirements of the programme than just one. In addition given the older age group of the population it is possible that the potential 'support' individual may have had a chronic illness or disability of their own, making it difficult for either the person with diabetes to request the attendance of their partner, or their partner being able to attend the programme.

A second possible reason for lack of acceptability of the social support intervention was lack of interest in learning social support skills. It is of note that the population targeted were from older age groups. As a consequence it is likely that where partners were present the relationship was of long duration and the patterns of social interaction were

well established. It is possible that social support skills were not felt to be relevant. Support for this view was found in the response given by one couple who commented that 'after 40 years of marriage, you're not going to change the way you communicate now.' A question remains as to whether interest in a social support intervention would have been different if a younger population, or individuals in less well established relationships, were targeted.

As uptake into the social support programme was so low this arm of the trial was closed. Consequently the independent benefit of social support skills training when added to a standard SMI could not be evaluated. These findings did however highlight the importance of trial design in evaluating SMIs. The current study used a part-randomised patient preference design in contrast to a traditional RCT. It was argued in chapter five that an RCT is inappropriate when not all individuals have the capacity to be allocated to each of the treatment options i.e. because no partner is present or because of lack of interest in attending with a partner. The lack of uptake of the social support intervention, even amongst individuals who had partners, suggests that if an RCT with random allocation into all three arms had been used, then overall uptake into the study would have been far lower. Besides the limitations of this to generalisability of study results, recruitment times would have been likely to have been significantly longer than was achieved.

Once an individual consents to a trial, the acceptability of the intervention is further indicated by compliance to the intervention protocol, or 'drop-out' from the intervention. In the current study, 'drop-outs' were classified as individuals who attended 4 or less of the 6 sessions. Fifteen percent of the intervention sample satisfied this definition. In contrast to other studies rate of attrition from the SMI was low. For example in a review

by Norris *et al.,* (2002a) it was reported that over one third of studies have greater than 20% attrition, although it is not clear whether this is attrition from just the intervention or the study as a whole.

In the current sample the only difference between 'drop outs' and participants was that 'drop outs' had significantly higher baseline HbA1c. This could suggest that individuals who dropped out already had greater difficulty controlling their diabetes and could imply that they were less engaged in the concept of self-management than those who completed the programme. The implications of this for use of the UCL-DSMP with different populations is important, and will be discussed in more detail in chapter fourteen.

Although intervention attrition provides a crude index of the acceptability to a participant, participants' reasons for non-attendance provide a more detailed approach. In the current study the reasons given for inability to attend individual sessions were ill health of self or spouse, work commitments, or holiday arrangements. No individual stated that sessions 'being unhelpful' was a reason for not attending. However in examining the reasons for non-attendance it should be considered that an individual may give excuses rather than say they found sessions unhelpful. Seven of the ten drop-outs however missed early sessions but attended later sessions suggesting that the reasons they provided were true.

Uptake and intervention attrition give some indication of programme acceptability but these are only indirect measures. Direct assessment of acceptability could use either interview or questionnaire methodologies. These techniques were not included in the current study for a number of reasons. Firstly to the author's knowledge no valid and

reliable assessment of satisfaction with this type of intervention was available at the time of study design. Although the Diabetes Treatment Satisfaction Questionnaire (Bradley, 1996b) was available, this measure focused primarily on satisfaction with pharmacological treatments and interventions (for example use of insulin regimens). This was not felt to be appropriate for evaluating a SMI. Subsequent to the initiation of the current study a new assessment tool, the Diabetes Management Evaluation Tool (Paddock, Veloski, Chatterton, Gevirtz & Nash, 2000), has been published. This tool was specifically designed to assess patient satisfaction with diabetes disease management programmes. Although not specific to SMIs, this measure does cover a number of important aspects that are relevant to SMIs including the practicalities of meetings, usefulness of information learnt, understanding of behaviours and complications etc. Future SMIs may therefore find this a useful tool for evaluation of acceptability.

Participant interviews were not conducted in the current study with the exception of participants attending the pilot sessions. A difficulty with interview assessments in this context is again social desirability bias. This is especially the case if the interview is performed by an individual, whom the participant knows to be involved in the research project. This can be overcome if an independent interviewer is used, however this was not practical in the current study. In addition for both use of questionnaires or interviews there was concern about assessment burden on participants with the potential to lead to higher attrition.

9.3 Demonstration of the Effects of the UCL-DSMP on Clinical, Behavioural and Psychosocial Outcomes and Process Variables

Due to the closure of the social support arm, the analysis was restricted to a direct comparison of the UCL-DSMP, attended alone, and the standard treatment control group. Loss to follow-up ranged from 5% at IPI to 11% at both 3 and 9 months following the intervention. This is lower than has been reported in other studies (Glasgow *et al.,* 1996; Newman *et al.*, 2004). Although differences between those lost to follow-up and those who completed assessments were identified at each follow-up, there was no consistent or coherent pattern to these differences. It is also possible that results found to be significant may have been spurious given the number of comparisons made.

9.3.1 Clinical Outcomes

The primary clinical outcome that was assessed in this study was HbA1c. An effect of the SMI on this variable was not demonstrated, with non significant differences found between the groups at both 3 months and 9 months follow-up. The intervention group did however show a significant improvement between baseline and 3 months follow-up, which was not demonstrated by the control group. The positive effect on within group analysis is similar to findings from pre-post trials (see for example Sakardi & Rosenqvist, 2001; Fritshe *et al.*, 1999; Gruesser *et al.*, 1996), however comparison to control groups is the stronger indicator of efficacy. Previous SMIs based on social cognitive theory have in general found significant effects (Di Loretto *et al.*, 2003; Miller *et al.*, 2002; Glasgow *et al.*, 2003; Agurs-Collins *et al.*, 1997), so the results of the current study are disappointing.

A number of reasons could account for this lack of efficacy. One possibility is that the study was underpowered. A priori power calculations estimated a need for 60

participants per study arm allowing for 10% drop-out, hence a total sample of 54 participants per arm was required for sufficient power to assess this outcome. At 3 months follow-up HbA1c was analysed for 46 intervention group participants and 53 control group participants, and at 9 months follow-up 49 intervention group and 54 control group participants. The study was therefore slightly underpowered, particularly with respect to the intervention group.

Participants in the current study also had lower baseline HbA1c levels than was initially expected for this population. Approximately one third of participants had an HbA1c below 7.5%mmol, which is the target as specified in recent guidelines (National Institute for Clinical Excellence, 2002). The current population was expected to have higher HbA1c levels at baseline because of the inclusion criteria of microalbuminuria and proteinuria, which is usually associated with poor blood glucose control. However it may be that once participants have been diagnosed with microalbuminuria they may be more intensively treated by physicians in order to bring their blood glucose under control. Also those who were aware of their microalbuminuria may also have attempted to lower their HbA1c. It is also of note that intervention 'drop-outs', who were excluded from efficacy analysis, had higher baseline HbA1c levels than individuals completing the intervention, this lowered baseline HbA1c, particularly in the intervention group, even further. The reason that lower baseline HbA1c may influence demonstration of efficacy of SMIs is because it is harder to achieve change in HbA1c when initial values approach normal (4%-6%) (Pickup, 1997) than when initial values are high as the magnitude for change is lessened. Therefore in demonstrating intervention efficacy on this variable many studies specifically select participants with high HbA1c. Alternatively an approach commonly used to overcome such difficulties with other biological measures is to calculate log scores. This approach has been used infrequently in diabetes SMIs however, and such

analysis was therefore not conducted in the current study, to enable comparison with other studies.

A second clinical variable that was measured at baseline but not evaluated for efficacy was blood pressure. Although this is an important clinical variable a number of practical difficulties meant that in the current study evaluations of this measure were not reliable. At baseline blood pressure could not be measured for a total of 32 (26%) participants. These were predominantly individuals with large arm circumferences. Although an extra large cuff was purchased for use with such participants, error messages were frequently achieved when measuring blood pressure with these participants. The pattern of missing data for blood pressure was therefore not random and hence imputation was not performed and this variable was excluded from further analysis.

Difficulties were also incurred for assessment of changes in medication. At baseline data was collected on type, dose and frequency of medication. The aim was to collect the same data at follow-up, hence enabling calculation of change in medication to be detected. Change in medication has been highlighted as an important outcome of SMIs (Loveman *et al.*, 2003) as change in self-management behaviours may be expected to result in changes in medication, which has implications both for an individual's QoL and health service resources. The current study relied on participants' self-reports for this variable and difficulties were encountered on data collection at follow-up. A number of participants did not know specific doses of their medications, and did not bring their medication to assessments. Also where participants completed questionnaires at home this item was often completed incorrectly, with many participants reporting just the name of the medication but not frequency or dose. Although attempts were made to verify patient medication by cross reference with the hospital database it became apparent that

this data was not always recorded, and was sometimes inaccurate, particularly if changes had been made by a participant's GP. The large amount, and non-random nature, of the missing data on this variable therefore meant it was excluded from analysis.

9.3.2 Self-Management Behaviours

The UCL-DSMP had a significant positive impact on all dietary behaviours at IPI. However although levels did not fall back to baseline in the intervention group, and were higher than baseline levels for both fat consumption and general dietary behaviours at 3 months, there was no difference between control and intervention groups on any dietary outcome at 3 or 9 months. The intervention therefore improved dietary behaviour in the short-term but this was not retained in the long term. The short-term improvement on dietary behaviour is in line with previous research (see for example Glasgow *et al.*, 2003, 1992; Kenardy *et al.*, 2002; Vazquez *et al.*, 1998; Wing *et al.,* 1991, 1988, 1986).

A number of factors, other than the SMI lacking sufficient efficacy, could contribute to the lack of effect in the long-term. For general dietary behaviour at 3 and 9 months follow-ups the control group were observed to increase dietary behaviour from baseline. The increase in general dietary behaviour in the control group makes differences between the two groups more difficult to demonstrate, as a greater change from baseline is necessary in the intervention group than otherwise required. This is a particular difficulty when baseline levels of behaviour are high and potential ceiling effects can occur. As discussed in chapter seven, baseline levels of both general dietary and specific dietary behaviours were high in the current study (dietary guidelines followed approximately 5 days per week), and higher than has been reported in previous studies in the UK (Clark & Hampson, 2001). The reaching of near ceiling levels in the intervention group at IPI

made it difficult for any additional increases, necessary to compensate for the increases in dietary behaviour in the control group, to occur.

Although improvement in the control group may explain poor maintenance of effect for general dietary behaviours, this was not the case for consumption of fruit and vegetables or avoidance of a high fat diet, as the control group showed slight decreases compared to baseline at each assessment period. It may be speculated that the SMI did not address these specific behaviours in sufficient detail; alternatively these behaviours may be more difficult to maintain changes in over the longer term. Increasing consumption of fruit and vegetables appears to be the behaviour most difficult to maintain change in as no effect was seen either on within group or between groups analyses, at either 3 or 9 month follow-ups. This is in contrast to avoidance of a high fat diet, which showed a trend ($p<0.06$) towards differences between groups at 3 months, and was also significantly different from baseline in the intervention group at this point.

When looking at behaviour change it is possible that there may be a ceiling to the frequency with which people will regularly carry out certain behaviours. For example it could be questioned whether it is realistic to expect individuals to follow a healthy diet, including avoiding high fat foods, on more than 6 out of 7 days a week, or to eat five or more servings of fruit and vegetables on more than 5 out of 7 days a week? If there is a ceiling to such behaviours then it is less surprising that effects of the intervention were not maintained on these behaviours in the current study.

Unlike for dietary behaviours, exercise behaviour was not influenced by ceiling effects as this behaviour was only performed on 2 days per week at baseline. Individuals receiving the intervention significantly improved relative to the control group on exercise behaviour

at all assessment periods, and levels were significantly greater than baseline in the intervention group at all follow-ups. An improvement in exercise behaviour is of note because previous interventions have not been consistent in demonstrating an effect on exercise. What is of interest is that those SMIs using theoretically based models such as the TTM or SCT, as used in the current study, were more likely to have a beneficial effect (see for example Tudor-Locke *et al.*, 2002; Kirk *et al.*, 2003; Di Loretto *et al.*, 2003; Agurs Collins *et al.*, 1997; Glasgow *et al.*, 1992). An improvement in exercise behaviour is also important given the traditionally low levels of exercise behaviour for much of the diabetic population (Nelson *et al.*, 2002; Hays & Clark, 1999) and the benefits that exercise has for both physical and psychological well-being (Duncan *et al.*, 2003; Salmon, 2000). Maintenance of exercise in the long-term was also significant. Although some exercise specific interventions for individuals with type 2 diabetes have maintained changes in exercise for more than 6 months (Kirk *et al.*, 2003; Di Loreto *et al.*, 2003), only one general SMI study, of those reported in chapter three, has achieved such an effect (Keyserling *et al.*, 2002).

Following the self-management programme, individuals in the intervention group also monitored their blood sugars significantly more frequently than the control group and significantly more often than at baseline. This initial benefit was maintained over time with significant differences between the groups present at 3 and 9 months follow ups. Other SMIs frequently report similar improvements in SMBG (see for example Trento *et al.*, 2004; Fritshe *et al.*, 1999; Smith *et al.*, 1997). Although the impact of monitoring blood sugars on glycaemic control is unclear and under debate (Coster *et al.*, 2000) it is generally believed to be an important tool when combined with training in other self-management behaviours such as diet and exercise behaviour (Schwedes *et al.*, 2002). However although the impact of the UCL-DSMP on SMBG appears clear it could be

questioned whether the improvement in the intervention group is due to more frequent monitoring amongst individuals who have previously monitored or whether the figures are simply influenced by the initiation of monitoring amongst individuals previously not advised to monitor blood glucose in the intervention group. Two issues are important with regard to this point. Firstly it is not unreasonable to argue that the initiation of SMBG is an important outcome in its own right. Secondly unlike diet and exercise an unconditional increase in frequency of SMBG is not necessarily an appropriate target of an SMI, rather testing at a level appropriate for each individual should be the aim. These points would suggest that more detailed examination of SMBG in future studies would be helpful.

The one self-management behaviour that was not changed by the intervention at any follow-up was smoking. Smoking cessation is important for all individuals with diabetes because of its association with increased insulin resistance and implications for the development of complications (Targher *et al.*, 1997; Haire-Joshu *et al.*, 1999). However, within the current sample relatively few individuals (18%) smoked at baseline. This is a somewhat lower rate than previously reported in diabetes (26%) (Ford, Malarcher, Herman & Aubert, 1994). The small number of smokers made it difficult to observe a statistically significant effect of the intervention. Smoking was also not a topic specifically addressed within the intervention. The reason that smoking was not a key focus of the intervention was that during discussions with health care professionals, and focus groups with patients, smoking was not raised as an issue of relevance for the majority of individuals.

Although smoking was not specifically addressed as a topic in the SMI individuals who raised giving up smoking as a difficulty were advised to apply the problem solving

techniques that they had learnt from the programme, and encouraged to set behavioural goals and rewards for this behaviour. By the end of the study approximately one third of intervention participants had given up smoking while only approximately one tenth of control participants had. This suggested that some individuals who smoked were able to apply the general strategies taught in the intervention to this area. Although the effect was not statistically significant this may be due to lack of power rather than lack of efficacy of the SMI.

The self-management programme showed at least some effects on diet, exercise and SMBG. It was also of interest that the control group showed a pattern of increased general diet, exercise and SMBG behaviours between baseline and follow-up assessments. One explanation for this could be the Hawthorne Effect (Franke & Kaul, 1978). This phenomenon states that by simply taking part in a study, and being observed, an individual's behaviour and other outcomes will be improved. In addition completion of questionnaires may have sensitised all participants to the behaviours that are recommended for care. The occurrence of such effects emphasises the importance of any evaluations of SMIs to include a comparison group.

An additional explanation for improvements in the control group was that even though they were receiving no planned intervention, inadvertent intervention may have been occurring. This is possible where facilitators of the programme, who having been trained in specific techniques and approaches, use these skills externally to the programme and within their standard care of patients. In this study attempts were made to minimise this effect. A practice nurse who was not involved in care of participants outside of the programme sessions, was selected as the main programme facilitator. For practical reasons the diabetes specialist nurses and dieticians who both contributed to two

sessions per group, were however responsible for the standard care of all participants. It is therefore possible that inadvertent contamination may have occurred from the diabetes specialist nurse present in sessions one and four and the dietician present in sessions two and three. The difficulty of intervention contamination is a common difficulty within SMIs. To overcome this difficulty ideally no facilitators should be involved in the routine care of participants in the trial, unfortunately this is often difficult to achieve.

9.3.3 Quality of Life

The current SMI demonstrated improvement on diabetes specific QoL relative to the control group at all follow-ups. At IPI this appeared to be due to improvement in QoL amongst the intervention group. However at 3 months follow-up, although the intervention group had not regressed back to baseline, the difference in groups appeared to be due to deterioration in QoL in the control group. This pattern of improvement in the intervention group and deterioration in the control group relative to baseline was also retained at 9 months. This suggests that the current intervention had the effect of both improving QoL at IPI and preventing deterioration of QoL in the longer term.

The findings on the diabetes specific QoL measure were not replicated when assessment used the generic QoL measure (SF-36). No differences were found between groups at any follow-up assessment. It has previously been argued that diabetes specific measures are more sensitive to change following SMIs than generic measures (Steed *et al.*, 2003). The results of the current study support this assertion and would suggest that future studies in diabetes should use illness specific measurement tools for assessing QoL.

A surprising finding of the current study was the deterioration from baseline to IPI within the intervention group on the SF-36 PCS. Although the possibility of SMIs leading to increased burden for participants through increased self-management behaviours has been raised previously (Watkins *et al.*, 2000), there is little evidence to support this in reviews of the literature (see Steed *et al.*, 2003 and discussion chapter three). In the current study although the presence of microalbuminuria was an inclusion criteria, it became apparent during the self-management programme that some participants were unaware of this diagnosis. It is conceivable that this information, about the presence of a previously unknown complication, may have influenced an individual's perception of their physical functioning immediately following the intervention. However this effect was not retained, as at 3 and 9 months follow-ups, scores on the SF-36 PCS were no different to baseline. That a number of participants were not aware of their diagnosis of microalbuminuria, raises questions over how informed individuals are about their condition This could suggest the need for an individual review of the clinical state and knowledge of each participant prior to consent into a study.

9.3.4 Psychological Well-Being

The intervention did not show an effect on any of the dimensions of negative well-being that were assessed, including depression, anxiety, or negative affect. Previous reviews looking at the impact of SMIs on psychological well-being in diabetes have suggested that interventions are more likely to be efficacious if they include cognitive behavioural therapies and are targeted at populations with clinical depression or anxiety (see Steed *et al.*, 2003 and chapter three for discussion). The current study could not be described as a cognitive behavioural intervention. In addition mean levels of depression and anxiety at baseline reflected no evidence of clinical symptoms. It was therefore not

surprising that change in psychological well-being was not found. Subgroup analysis with only those individuals classified as having scores on the HAD Scale reflective of probable clinical disorders also did not indicate an effect of the intervention. However as this included only 3 and 7 individuals for depression and anxiety respectively, this analysis was significantly underpowered.

Evidence suggests that negative aspects of well-being are unlikely to be affected by SMIs, unless the intervention is designed for this purpose and evaluated in an appropriate population. It is unclear, however, whether this is also true for positive aspects of well-being. Three studies included in the systematic review presented in chapter three measured aspects of positive well-being in type 2 diabetes (Kirk *et al.*, 2001; Kenardy *et al.*, 2002; Glasgow *et al.*, 1992). Both Kirk *et al.*, (2001) and Kenardy *et al.,* (2002) used the well-being questionnaire. which assesses depression, anxiety, energy and positive well-being, and Glasgow *et al.*, (1992) used the Pleasant Events Schedule for Older People. Neither Kirk *et al.*, (2001), nor Glasgow *et al.*, (1992), demonstrated any effect of their SMI on these outcomes. Kenardy *et al.*, (2002) did report intervention benefits, however results were not reported for sub-scales of the well-being scale, hence it is unclear if positive well-being was improved. The current SMI did not demonstrate any effect on positive well-being as assessed by the PANAS. Although the current evidence on positive well-being is not promising in type 2 diabetes it has been assessed infrequently. It remains a useful measure for studies as it is plausible that improved control over diabetes may lead to increases in positive well-being.

9.3.5 Process Measures

The process measure that has most frequently been included within evaluations of SMIs is knowledge. This has been consistently demonstrated to improve following SMIs

(Norris *et al.*, 2001; Padgett *et al.*, 1988). In common with previous studies the intervention group in the current study demonstrated significantly better knowledge scores relative to the control group at both IPI and 3 months follow-up. The inclusion of knowledge assessments has been criticised in some reviews, in particular when it is to the exclusion of other process variables (Glasgow & Osteen, 1992). The current study included a range of process and outcome variables along with knowledge. However because knowledge is deemed necessary for behaviour change it was felt important to ensure that levels were at an adequate level.

Process variables other than knowledge were selected on the basis of the theoretical models that were used in developing the intervention. From SCT self-efficacy was assessed. No changes in self-efficacy as a result of the SMI were seen until 3 months follow-up when self-efficacy for both exercise and SMBG had significantly increased relative to the control group. These increases were not maintained for exercise self-efficacy at 9 months follow-up but were for SMBG. These findings are important, as only a few SMIs have previously assessed self-efficacy (Glasgow *et al.*, 2002, 1992; Peyrot & Ruben, 1999; Anderson *et al.*, 1995). Four out of five of these interventions (including the current SMI) have had an effect on this variable. All of these interventions were explicitly based on empowerment or SCT and hence included components such as problem solving, goal setting and behavioural strategies. These strategies can therefore be considered as being useful for improving self-efficacy in SMIs.

As with all process measures, it is not simply the increase in self-efficacy per se that is of interest but rather whether this acts as a mediating factor in changing self-management behaviours or other important outcomes. This is examined in more detail in chapters ten & eleven. It is interesting however that both in the current study and that by Glasgow *et*

al., 2002, there was a delayed effect on self-efficacy at 3 and 12 months respectively. This raises the possibility that change in another variable, possibly behaviour, may be required before self-efficacy is influenced. The extent that behaviour mediates change in self-efficacy is discussed further in chapters ten & eleven.

A further result of interest in relation to self-efficacy in the current study is the finding that an effect of the intervention was only demonstrated on the behaviour specific self-efficacy scales and not the composite measure. Although the behaviour specific scales in the current study are limited by being only one item, it reinforces the importance of specificity when assessing self-efficacy.

The other construct most frequently assessed from Bandura's SCT is outcome expectancies. This was not assessed in the current study as previous research has not demonstrated association between OEs and behaviour (Skelly *et al.*, 1995; Williams & Bond, 2002; Hays & Clark 1999; Vincze *et al.*, 2004) or psychological well-being (Connell *et al.*, 1994).

The second theory used to guide the development of the current SMI was SRM. Personal models of diabetes were therefore assessed and targeted in the intervention. The current intervention did not effect how seriously individuals perceived their diabetes to be. This was even though some individuals did not know about their diagnosis of microalbuminuria at baseline. The lack of change in beliefs in seriousness could be because at baseline individuals already perceived their diabetes as fairly serious. In addition the intervention taught individuals that although diabetes is a serious condition its implications could be minimised by taking appropriate control, via engaging in self-

management behaviours, and managing blood glucose and blood pressure levels, so as to avoid complications.

The intervention demonstrated efficacy on perceived control over blood glucose as indicated by the significant differences between groups on personal models of control at IPI. This was attributable to the intervention group increasing sense of control from baseline whilst there was no change in the control group. Although at 3 and 9 month follow-ups the groups were no longer significantly different on this outcome, the intervention group continued to show a significant change from baseline to 3 months, which was not apparent in the control group. It is interesting that the effect of the intervention on perceived control was seen at IPI whilst the effect on self-efficacy was not observed until 3 months follow-up. The variable of perceived control over blood glucose could be considered similar to other measures of control e.g. internal locus of control. This latter construct has been shown to increase following an empowerment intervention (Keers *et al.*, 2004), but not following basic education or support group interventions (D'Eramo Melkus *et al.*, 1992; Maxwell *et al.*, 1992). The extent of the similarities and differences between constructs such as locus of control, perceived control and self-efficacy are important to consider. Both locus of control and perceived control can be considered global measures of control. For example an individual could believe that they do have control over their blood glucose because they know that diet and exercise influence outcomes, which theoretically they can change, hence they would be high on personal control. However they may still be low on self-efficacy if they are not currently confident that they will exercise or follow a diet, particularly if significant barriers are present. The similarities and differences between different constructs of control are discussed by Trafimow, Sheeran, Conner & Finlay, (2002). The relative importance of these two forms of control for behaviour change in the current study is

also empirically elucidated through examination of their role as mediators (see chapters 10 & 11).

The third personal model construct assessed was treatment effectiveness. A significant effect of the intervention relative to the control group was found at IPI, and a trend ($p<0.07$) towards improvement at 3 months follow-up, however effects were not retained at 9 months follow-up. This construct has not frequently been included in evaluations of SMIs, with the exception of one study where a nurse led intervention, targeted specifically at patients' beliefs, increased participants' perception of treatment benefits. Taken together these studies tentatively suggest that SMIs can have a significant impact on belief in treatment effectiveness.

The third theoretical model used to guide the intervention was the TTM. RTC was the only construct from this model to be assessed and was only measured at IPI and 3 months follow-up. RTC diet, exercise, SMBG and medication taking behaviours were assessed separately. Only RTC diet was significantly improved in the intervention group relative to the control group, and only at 3 months follow-up. Although two previous SMIs have improved readiness to change (Kirk *et al.*, 2003; Jones *et al.*, 2003), in both of these studies the TTM was the only theory to guide intervention development. In the current study the TTM only guided intervention development to the extent that facilitators and participants were taught that when behaviour change is the target, the individual's starting point (or RTC) must be considered, and goals must be set in accordance with this. Other aspects of the TTM, e.g. processes of change were not explicitly addressed. It is therefore not surprising that efficacy of the intervention on this process measure was not stronger.

9.4 Conclusions

A social support self-management intervention attended with partners did not appear to be acceptable for the current population. A self-management intervention attended alone was more acceptable. This later intervention showed effects on behaviour, quality of life and a number of process measures at IPI, with some effects retained at 3 months post-intervention but few still apparent at 9 months. The implications of this for study design are discussed in more detail in chapter fourteen.

CHAPTER TEN: MEDIATOR ANALYSIS FOR CHANGE IN OUTCOMES FOLLOWING THE UCL-DSMP?

10.1 Structure of the Chapter

This chapter explores the extent to which change in self-management behaviours and diabetes specific QoL were mediated by change in process variables at each follow-up. Self-management behaviours and diabetes specific QoL were examined as the intervention programme had consistent significant effects on these outcomes. The process variables tested for as mediators were knowledge, behaviour specific self-efficacy, personal models of diabetes and RTC behaviour. These variables were tested as they were identified as potential mediators in the theories used to guide intervention development, i.e. SCT, SRT, TTM. At each follow-up, analysis was only conducted for outcome variables and process variables that had shown a significant intervention effect. Both concurrent and prospective mediation was explored. Single mediator models were tested, however where more than one mediator was identified for a dependent variable a multiple mediator model was also tested. This provided a more comprehensive understanding of the mediational process by examining whether a significant mediator in a single model was still significant when other mediators were present (MacKinnon *et al.,* 2001). When a significant mediator was identified in either a single or multiple mediator model the extent and significance of mediation was tested. Full details of the methods of mediation analysis have been described in chapter 5, section 5.7.4. including diagrams of the regression analysis conducted.

In the final section of the chapter the extent that self-management behaviours mediated change in behaviour specific self-efficacy is reported. This analysis was conducted to elucidate the relationship between change in self-efficacy and change in behaviour, as a result of findings and discussion in chapters 8 and 9.

10.2 Mediation of Change in Self-Management Behaviours at Immediate Post-Intervention

The intervention had a significant effect on all self-management behaviours at IPI (see table 10.1). However an intervention effect was only seen for knowledge and the personal models constructs of treatment effectiveness and control out of the process variables (see table 10.1). These were therefore the only variables tested for as mediators.

Table 10.1 Effect of the Intervention Programme on Self-Management Behaviours and Process Variables Immediately Post-Intervention.

Self-Management Behaviours	Intervention Effect B (SE)
General Diet	**0.76 (0.23)*** **
Fruit & Vegetable Consumption	**1.62 (0.44) *** **
Fat Consumption	**0.80 (0.27)***
Exercise	**1.34 (0.34) *** **
SMBG	**1.81 (0.39)*** **
Process Variables	
Knowledge	**10.82 (2.56)*** **
Self-Efficacy Diet	2.62 (2.93)
Self-Efficacy Exercise	6.53 (3.79)
Self-Efficacy SMBG	4.08 (4.06)
Personal Models - Seriousness	0.10 (0.12)
Personal Models - Treat Effectiveness	**0.26 (0.08)*** **
Personal Models- Control	**0.29 (0.15)***
RTC- Diet	0.30 (0.23)
RTC- Exercise	-0.06 (0.25)
RTC- SMBG	-0.02 (0.22)
RTC- Medication	0.06 (0.26)

RTC – Readiness to Change * p<0.05, ** p< 0.01, ***p<0.001

Table 10.2 shows the coefficients of mediation analysis for each of the self-management behaviours. No significant mediators were identified for change in

either general dietary behaviour, frequency of fruit and vegetable consumption or SMBG. Change in personal models of control was identified as a mediator of change in consumption of fat between baseline and IPI, however the amount of mediation was not significant B=0.12 (0.08) (Z=1.525, p>0.05). Similarly although change in personal models of control was identified as a mediator of change in exercise between baseline and IPI the amount of mediation was not significant B=-0.12 (0.09) (Z=-1.36, p>0.05).

Table10.2. Mediation Analysis of the Effect of Change in Potential Mediator on Change in Self-Management Behaviours at Immediate Post-Intervention

	Relationship of Change in Mediator to Change in Self-Management Behaviour (B(SE)				
Potential Mediator	General Diet	Fruit	Fat	Exercise	SMBG
Knowledge	0.00 (0.01)	-0.02 (0.02)	0.02 (0.01)	-0.00 (0.01)	0.01 (0.02)
Personal Models					
Treatment Eff.	0.10 (0.29)	-0.11 (0.56)	0.22 (0.34)	0.06 (0.43)	0.23 (0.50)
Control	0.10 (0.15)	-0.18(0.29)	**0.42(0.17)***	**-0.42 (0.22)***	0.22 (0.26)

*p<0.05, **p<0.01, *** p<0.001

10.3 Mediation of Change in Diabetes Specific Quality of Life at Immediate Post-Intervention

At IPI diabetes specific QoL was significantly predicted by the intervention (B=0.066 (0.28), p<0.05). Only change in belief in personal models of control was identified as a mediator of change in diabetes specific quality of life between baseline and IPI (see table 10.3). The extent of mediation was not significant B=-0.10 (0.07) (Z=-1.36, p>0.05).

Table10.3. Mediation Analysis of the Effect of Change in Potential Mediator on Change in Diabetes Specific Quality of Life at Immediate Post-Intervention

	Relationship of Change in Mediator to Change in ADDQoL (B (SE)
Potential Mediator	
Knowledge	-0.02 (0.11)
Personal Models	
Treatment Eff.	-0.45 (0.35)
Control	**-0.35 (0.18)***

*p<0.05, **p<0.01, *** p<0.001

10.4 Mediation of Change in Self-Management Behaviours at 3 Months Follow-Up

At 3 month follow-up an intervention effect was no longer seen for change in general dietary behaviour or fruit and vegetable consumption. A significant intervention effect was however found for change in fat consumption, exercise and SMBG behaviours (see table 10.4). For the process variables a significant intervention effect was demonstrated on change in knowledge ($p<0.01$), self-efficacy for exercise ($p<0.01$) self-efficacy for SMBG ($p<0.05$) and RTC dietary behaviour ($p<0.05$), hence these were the only potential mediators entered into regression analysis (see table 10.4).

As change in general dietary behaviour and fruit and vegetable consumption were not predicted by the intervention mediator analysis was not conducted on these behaviours. No significant mediators were identified for change in fat consumption in either concurrent (change in process variables between baseline and 3 months) or prospective (change in process variables between baseline and IPI) analyses.

Table 10.4 Effect of the Intervention Programme on Self-Management Behaviours and Process Variables at 3 Months Follow-Up.

Self-Management Behaviours	Intervention Effect B (SE)
General Diet	0.35 (0.23)
Fruit & Vegetable Consumption	0.57 (0.30)
Fat Consumption	**0.62 (0.30)***
Exercise	**0.72 (0.35)***
SMBG	**1.09 (0.44)***
Process Variables	
Knowledge	**11.02 (2.26)*****
Self-Efficacy Diet	3.18 (2.63)
Self-Efficacy Exercise	**9.05 (3.19)****
Self-Efficacy SMBG	**8.69 (4.30)***
Personal Models - Seriousness	0.11 (0.12)
Personal Models - Treat Effectiveness	0.13 (0.08)
Personal Models- Control	0.25 (0.14)
RTC- Diet	**0.32 (0.15)***
RTC- Exercise	-0.04 (0.25)
RTC- SMBG	0.36 (0.19)
RTC- Medication	0.08 (0.26)

* $p<0.05$, ** $p< 0.01$, ***$p<0.001$

Two mediators of change in exercise behaviour at 3 month follow-up were identified. These were change in knowledge between baseline and 3 months and change in exercise self-efficacy between baseline and 3 months (see table 10.5). The mediated effect of knowledge was B=0.38 (0.13) (Z=2.88, $p<0.05$) and for self-efficacy for exercise was B=0.24 (0.12), (Z=1.96, $p<0.05$). In both cases the amount of mediation was significant. When entered together in a multiple mediator model both were still identified as significant mediators, however in both cases the extent of mediation was non-significant (Knowledge – B=0.36 (0.19) (Z=1.85, $p>0.05$); self-efficacy for exercise B=0.23 (0.12) (Z=1.88, $p>0.05$)).

Table10.5. Mediation Analysis of the Effect of Change in Potential Mediator on Change in Self-Management Behaviours at 3 Months Follow-Up

	Relationship of Change in Mediator to Change in Self-Management Behaviour (B(SE)			
	Fat	Exercise		SMBG
Potential Mediators	Single Mediator Model	Single Mediator Model	Multiple Mediator Model	Single Mediator Model
Change BL-3Mths				
Knowledge	0.01 (0.01)	**0.03 (0.01)***	**0.032 (0.02)***	0.00 (0.02)
Self-Efficacy Exercise		**0.03 (0.01)***	**0.025 (0.01)***	
Self-Efficacy SMBG				**0.04(0.01)****
RTC –Diet	0.17 (0.22)			
Change BL-IPI				
Knowledge	0.02(0.01)	0.02(0.02)	-	-0.01(0.02)
Personal Models				
Treatment Eff.	-0.30 (0.41)	-0.32(0.47)	-	-0.27(0.60)
Control	0.35 (0.19)	0.27 (0.23)	-	0.13 (0.29)

BL- Baseline, IPI- Immediate Post Intervention, * p<0.05, ** p< 0.01, ***p<0.001

Change in self-efficacy for SMBG between baseline and 3 months was identified as a significant mediator of change in SMBG at 3 months follow-up, however the amount of mediation was not significant B=0.32 (0.18) (Z=1.34, p>0.05).

10.5 Mediation of Change in Diabetes Specific Quality of Life at 3 Months Follow-Up

A significant intervention effect on diabetes specific quality of life was shown at 3 month follow-up B=0.79 (0.28), p<0.01. The effect of potential mediators, both concurrent and prospective is shown in table 10.6. Only change in personal models of control between baseline and IPI was identified as a mediator. The amount of mediation for this variable was B=0.113 (0.08) (Z=-1.467, p>0.05) which was not significant.

Table10.6. Mediation Analysis of the Effect of Change in Potential Mediators on Change in Diabetes Specific Quality of Life at 3 Months Follow-Up

Potential Mediators	**Relationship of Change in Mediator to Change in ADDQoL (B (SE)**
Change BL-3Mths	
Knowledge	0.02 (0.01)
Self-Efficacy - Exercise	-0.01 (0.01)
Self-Efficacy SMBG	0.00 (0.01)
RTC Diet	-0.03(0.19)
Change BL-IPI	
Knowledge	-0.00 (0.01)
Personal Models	
Treatment Eff.	-0.27 (0.38)
Control	**-0.39 (0.18)***

BL- Baseline, IPI- Immediate Post Intervention, * p<0.05, ** p< 0.01, ***p<0.001

10.6 Mediation of Change in Self-Management Behaviours at 9 Months Follow-Up

Exercise and SMBG were the only self-management behaviours on which an intervention effect was found at 9 months follow-up (see table 10.7). Of the process variables knowledge and RTC behaviours were not measured at 9 months follow-up and hence were not reported. A significant intervention effect was found on change in self-efficacy for SMBG but not for other process variables at 9 months follow-up (see table 10.7)

Table 10.7 Effect of the Intervention Programme on Self-Management Behaviours and Process Variables at 9 Months Follow-Up.

Self-Management Behaviours	Intervention Effect B (SE)
General Diet	-0.14 (0.32)
Fruit & Vegetable Consumption	0.84 (0.49)
Fat Consumption	0.44 (0.36)
Exercise	**0.81 (0.36)***
SMBG	**1.00 (0.48)***
Process Variables	
Self-Efficacy Diet	-1.79 (3.52)
Self-Efficacy Exercise	4.32 (5.33)
Self-Efficacy SMBG	**15.06 (5.72)****
Personal Models - Seriousness	-0.08 (0.14)
Personal Models – Treatment Effectiveness	-0.08 (0.07)
Personal Models- Control	0.00 (0.15)

* p<0.05, **p<0.01, *** p<0.001

Table10.8. Mediation Analysis of the Effect of Change in Potential Mediators on Change in Self-Management Behaviours at 9 Months Follow-Up

Potential Mediator	**Relationship of Change in Mediator to Change in Self-Management Behaviour (B(SE)**	
	Exercise	**SMBG**
Change BL-9 Mths		
Self-Efficacy SMBG	-	**5.97 (1.01)*****
Change BL-3Mths		
Knowledge	-0.00 (0.02)	-0.01 (0.02)
Self-Efficacy Exercise	0.02 (0.01)	-
Self-Efficacy SMBG	-	**0.05 (0.01)*****
Change BL-IPI		
Knowledge	-0.00 (0.01)	0.00 (0.02)
Personal Models		
Treatment Eff.	0.08 (0.47)	0.52 (0.62)
Control	-0.21 (0.24)	-0.03 (0.32)

BL- Baseline, IPI- Immediate Post Intervention, * p<0.05, ** p< 0.01, ***p<0.001

Change in self-efficacy for SMBG between baseline and 9 months was identified as a significant mediator. The amount of mediation was B=89.99 (37.40) (Z=2.406, p<0.01) which was significant. Change in self-efficacy for SMBG between baseline and 3 months was also identified as a mediator however the amount of mediation at this point was not significant 0.434 (0.23) (Z=1.87, p>0.05).

10.7 Mediation of Change in Diabetes Specific Quality of Life at 9 Months Follow-Up

A significant intervention effect was found on diabetes specific quality of life at 9 months follow-up B=0.586 (0.2 7) p<0.05, however no mediators, either concurrent or prospective were identified (see table 10.9)

Table10.9. Mediation Analysis of the Effect of Change in Potential Mediators on Change in Diabetes Specific Quality of Life at 9 Months Follow-Up

Potential Mediator	**Relationship of Change in Mediator to Change in ADDQoL (B(SE)**
Change BL-9 Mths	
Self-Efficacy SMBG	-0.01 (0.01)
Change BL-3Mths	
Knowledge	0.02 (0.01)
Self-Efficacy Exercise	-0.01 (0.01)
Self-Efficacy SMBG	-0.01 (0.01)
RTC Diet	0.09 (0.15)
Change BL-IPI	
Knowledge	-0.01 (0.01)
Personal Models	
Treatment Eff.	-0.13 (0.36)
Control	-0.34 (0.18) p=0.06

BL- Baseline, IPI- Immediate Post Intervention, * p<0.05, ** p< 0.01, ***p<0.001

10.8 Mediation of Change in Self-Efficacy by Self-Management Behaviours at Each Follow Up

An intervention effect was only found for change in dietary self-efficacy at IPI, hence mediation analysis by change in dietary behaviour was only tested at IPI. Change in general diet and consumption of fruit and vegetables were not identified as mediators of self-efficacy for diet, however change in consumption of fat from baseline to IPI was identified as a mediator (see table 10.10). The amount of mediation was not significant B=2.069 (1.118) (Z=1.85, p>0.05).

Table10.10 Mediation Analysis of the Effect of Change in Self-Management Behaviours on Change in Self-Efficacy at Each Follow-Up

Potential Mediator	**Relationship of Change in Mediator to Change in Self-Efficacy (B(SE)**					
	Self-Efficacy Diet	Self-Efficacy Exercise		Self-Efficacy SMBG		
	IPI	IPI	3 Mths	IPI	3 Mths	9 Mths
Change BL-IPI						
Gen. Diet	1.36 (1.30)	-	-	-	-	-
Fruit	0.40 (0.67)	-	-	-	-	-
Fat	**2.58 (1.09)***	-	-	-	-	-
Exercise	-	1.39(1.14)	0.11 (0.97)	-	-	-
SMBG	-	-	-	**2.67 (0.98)****	**2.79 (1.08)***	**4.89(1.37)*****
Change BL-3mth						
Exercise	-	-	**2.11 (0.89)***	-	-	-
SMBG	-	-	-	-	**2.99 (0.95)****	**4.24 (1.25)*****
Change BL-9mths						
SMBG	-	-	-	-	-	**5.97 (1.01)*****

Intervention effects for change in exercise self-efficacy were identified at IPI and 3 months. Change in exercise behaviour from baseline to IPI was not a mediator of change in exercise self-efficacy at either IPI or 3 months. Change in exercise from

baseline to 3 months was however identified as a mediator of change in exercise self-efficacy from baseline to 3 months. The amount of mediation was not however significant B=1.649 (1.349) (Z=1.22, p> 0.05).

An intervention effect on SMBG self-efficacy was present at all follow-ups. Change in SMBG at IPI was identified as a mediator of change in SMBG self-efficacy at IPI, 3 months and 9 months (see table 10.10). The amount of mediation was B=4.838 (2.058) (Z=2.351, p<0.01) at IPI, B=5.055 (2.238) (Z=2.259, p<0.01) at 3 months follow-up and B=8.862 (3.130) (Z=2.831, p<0.01) at 9 months follow-up. At each follow-up the amount of mediation was significant. Change in SMBG at 3 months also mediated a significant amount of change in SMBG self-efficacy at 3 months B=3.244(1.67) (Z=1.94, p<0.05) and 9 months B=4.605 (2.309) (Z=1.99, p<0.01). Finally change in SMBG from baseline to 9 months mediated a significant amount of change in SMBG self-efficacy from baseline to 9 months B= 5.998 (3.039) (Z=1.974, p<0.05).

CHAPTER ELEVEN: DISCUSSION OF MEDIATORS OF THE UCL-DSMP

11.1 Structure of the Chapter

This chapter discusses the results of chapter 10, which explored mediators of change in behaviour and QoL. It was hypothesised a priori that behaviour change and improvement in QoL would be mediated by change in self-efficacy, change in illness representations (personal models) of diabetes, or change in RTC behaviour as predicted by SCT, SRT and the TTM respectively (see chapter 2 for more detailed discussion on theories). It was also hypothesised that increase in knowledge would not be a mediator as although information is necessary it is often not sufficient for behaviour change. The extent that these hypotheses were met is discussed and the implications of these for the theoretical models used in SMIs are considered.

11.2 Mediation of Change in Self-Management Behaviours

The prediction that change in knowledge would not mediate change in behaviour was largely supported in the current study. Although knowledge was consistently improved by the intervention it did not mediate change in diet or SMBG at any assessment point and only mediated exercise at the 3 months follow-up. This result, that change in exercise was mediated by change in knowledge at 3 months only, is an interesting finding. If individuals had not known at baseline that exercise was an important part of the diabetes management regimen then the increase in this knowledge following the SMI could be expected to increase behaviour. However knowledge would have been expected to be a mediator at IPI as well as at 3 months. The finding that exercise increased at IPI suggests that other, unidentified, factors were mediating the initial behaviour change and knowledge was not the critical mediator of change in exercise.

Change in exercise self-efficacy was also a mediator of change in exercise at 3 months. The amount of mediation by both change in knowledge and self-efficacy was significant in single mediator models, but not when entered together in a multiple mediator model. This would suggest some overlap between these two constructs and may explain why knowledge was only a significant mediator at 3 months follow-up, as this was the only point when change in self-efficacy for exercise was also a significant mediator of change in exercise.

The finding that change in exercise self-efficacy mediated change in exercise is as would be predicted from SCT. The finding that change in SMBG self-efficacy mediated change in SMBG, adds confidence to the importance of self-efficacy as a mediator of behaviour change in general. The effect of self-efficacy on behaviour change however was not immediate, as illustrated by the fact that mediation of change in behaviour by self-efficacy was only significant for exercise at 3 months but not IPI, and only significant for SMBG at 9 months and not earlier. This raises questions as to whether change needs to occur in other factors before change in self-efficacy can be a mediator of behaviour change. One question that was asked in the current study was whether change in behaviour is actually mediating change in self-efficacy. Although change in fat predicted change in dietary self-efficacy at IPI, and change in exercise predicted change in exercise self-efficacy at 3 months follow-up the amount of mediation in these relationships was not significant. Hence there is not strong evidence to support this relationship for diet or exercise. For SMBG however, change in SMBG concurrently and prospectively mediated a significant amount of change in SMBG self-efficacy from IPI to 9 months follow-up.

SMBG behaviour was somewhat different from either exercise or diet behaviour in this study because at baseline not all individuals knew what the behaviour involved or had been advised to undertake it. The current findings are therefore important as they could be taken to tentatively suggest that if a behaviour is unfamiliar then in the first instance behaviour must be performed which will increase self-efficacy which will further change behaviour. However where the behaviour is familiar, change in self-efficacy is more likely to drive behaviour change than vice versa. These complexities are recognised in SCT as it is suggested that mastery is an important mechanism of increasing self-efficacy (Bandura, 1997).

Change in diet was not mediated by change in dietary self-efficacy at any point. It may however be important that self-efficacy was assessed for diet in general. Self-efficacy for consumption of fruit and vegetables or fat intake was not assessed independently. The importance of specific measurement of self-efficacy has been discussed previously (see chapters 2 & 9) and the measurement of dietary self-efficacy may not have been sensitive enough to allow any mediation effect to be seen.

Change in an individual's RTC behaviour did not mediate change in any behaviour. This could be due to a weak intervention effect on RTC as only at 3 months follow-up and for dietary behaviour did the intervention have a significant effect. This finding would not be surprising as although the intervention drew on the TTM, particularly in helping individuals target behaviour change at an appropriate level, the intervention did not directly target other factors important for change in RTC behaviour. A lack of both intervention and mediation effect could also be contributed to by poor measurement of RTC, as in this study an un-validated questionnaire, with unknown sensitivity to change was used.

Constructs from the other theory to guide the development of the intervention, personal models of diabetes based on the SRM, were also not revealed as strong mediators of behaviour change. Perceived seriousness and treatment effectiveness, which have previously been associated and predictive of behaviour (Glasgow *et al.,* 1997b; Hampson *et al.,* 2000) did not mediate change in any behaviour at any time point. Change in personal models of control was identified as a mediator of change in exercise and SMBG between baseline and IPI, although the amount of mediation was not significant. It is interesting that belief about control was identified as a mediator of behaviour change only at IPI whilst self-efficacy was identified as a mediator only at later follow-ups. This supports the findings in chapters 8 & 9 that personal models of control and self-efficacy assess different conceptualisations of control. From the current study it could be suggested that an increase in general perceived control over blood glucose is necessary in the first instance before an individual is motivated to change behaviour, when behaviour specific self-efficacy becomes increasingly important.

11.3 Mediation of Change in Diabetes Specific Quality of Life

Change in belief about control over blood glucose was identified as a mediator of change in diabetes specific QoL at each follow-up. Although the amount of mediation was not significant at any assessment the consistency in the relationship is encouraging. The relationship was such that improvement in QoL was mediated by an increase in sense of control over blood glucose. These findings are similar to findings reported by Keers *et al.,* (2004) who reported that increased belief in internal locus of control predicted greater change in health change beliefs from the generic QoL measure the SF-36. In addition these results support studies which have indicated that better

psychological well-being is associated with greater perceived control (Macrodimitris & Endler, 2001) and sense of mastery (Pouwer *et al.,* 2003).

11.4 Limitations of Mediation Analysis

Although a number of mediators of change in self-management behaviours and QoL were identified in no instance was full mediation of an outcome variable explained. This suggests that other unidentified mediators were present in the current study. Factors such as decrease in perceived barriers to behaviour change, or increase in social support gained from being part of a group may have been important, unevaluated, mediators of behaviour change. As such variables were not assessed in the current study however it is impossible to explore this. Inferences from previous work is also limited as few studies of SMIs have conducted mediator analysis and with the exception of the work by Keers *et al.,* (2004) did not test theoretically based process variables as process measures.

In several instances when mediators were identified the amount of mediation was not significant. This may have been due to the mediator having a truly limited role in influencing the outcome or may have been related to methodological issues. Measurement error is one problem in mediation analysis as it reduces power (MacKinnon *et al.,* 2001), however many mediators, particularly those assessed by self-report, have measurement error. It has been suggested that use of multiple indicators of each variable can increase reliability (Aiken & West, 1991), however this was not practical in the current study. Multicollinearity as a result of the mediator being related to the programme as well as the outcome, also reduces power. To overcome these difficulties the use of reliable measures and large sample sizes are recommended.

A large sample size also allows for mediation analysis to be conducted through covariance structure modelling. This enables complex models to be built with more than one mediator and more than one outcome tested within the same model. Such models can also be longitudinal and include assessments at different time points. Although preferable, structural equation modelling requires large sample sizes of at least 300 (Joreskog, K., Personal Communication), otherwise the results can be unreliable and spurious relationships found. As the current sample did not meet this requirement this technique could not be used and a series of multiple regression analysis were conducted. Even using this more conservative analysis the small sample size and hence marginal N in the current study were still a cause for concern. Marginal N raises concern of insufficient power with the possibility that spurious relationships could be identified. Results of mediator analysis in the current study should therefore be treated with caution.

In the current study the role of several mediators was explored including variables from SCT, TTM, SRM and knowledge. This approach was taken to explore the relative efficacy of different theories in mediating behaviour change. Such an approach however increases the number of analyses conducted and risks spurious findings being detected. This is a particular problem where there is a limited sample as present in the current study. It therefore may have been preferable in the current study to be more theoretically driven, limiting the exploration of mediators to only variables from SCT or SRM.

The methodological difficulties described above may explain why only relatively weak mediation effects were seen in the current study and suggest that any interpretations should be treated cautiously. The importance of conducting mediator analysis, even when only exploratory, has however been reported previously by Baronwski *et al.*,

(1998) and MacKinnon *et al.,* (2001). They state that mediation analysis can test and inform the theories upon which programmes are based, can identify successful and unsuccessful components of programmes, and can lead to more efficient development of programmes. Analysis of mediators in the current study would suggest more support for SCT than the TTM or the SRM. However it also suggests that not all the mechanisms through which the programme is working have been identified and that measurement of some constructs in particular RTC may have been weak. The implications of these results for future research are discussed in chapter 14.

CHAPTER TWELVE: PREDICTION OF BENEFIT FOLLOWING THE UCL-DSMP

12.1 Structure of the Chapter

This chapter examines whether benefit from the UCL-DSMP can be predicted by baseline characteristics of participants. Residualised change scores (as described in chapter 5) for each outcome variable at each follow-up were calculated for the intervention group. Correlation analysis between baseline characteristics of participants and residualised change scores were conducted and used to select entry into regression analysis. Baseline variables that correlated significantly ($p<0.01$) with the residualised change score of the dependent variable, were entered into a regression analysis. In all equations demographic variables (age, educational level, gender) were forced into the equation at step one, and clinical variables (years diagnosed, HbA1c) were forced into the equation at step two, other baseline variables significantly associated with the dependent variable were entered at step three. It should be noted that prediction is of change scores, hence where it is reported that higher baseline scores on a variable predict improvement in the dependent variable, it should be recognised that the converse i.e. lower baseline scores predicting deterioration is also true.

Unlike in previous chapters where results have been ordered by follow-up periods, results in the current chapter are organised by outcome variable. This provides an easier comparison of whether the same baseline characteristic predicts change in the outcome variable at each follow-up.

12.2 Prediction of Change in Glycaemic Control Following the UCL-DSMP

Glycaemic control was not assessed at IPI. No baseline variables were significantly associated with residualised change scores of HbA1c at 3 months follow-up, hence regression analysis was not conducted at this point.

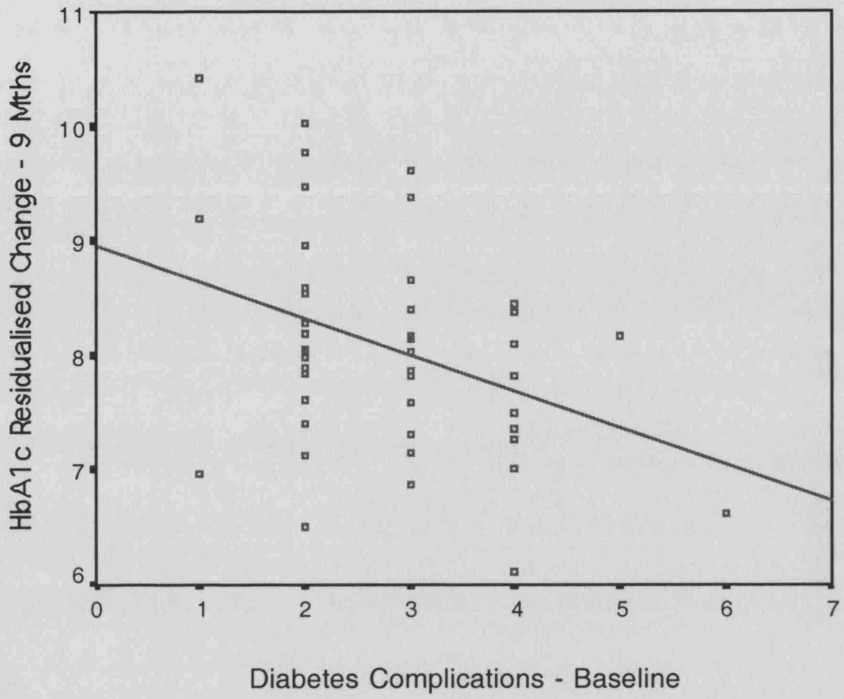
Table 12.1 Prediction of Residualised Change in HbA1c at 3 Months and 9 Months Follow-Up

	3 Month Follow-Up		9 Month Follow-Up	
Predictor Variables	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**
Step One	-	-	0.00	$F_{3,42} = 1.04$, P=0.39
Age				- 0.14
Educ. Qual.				0.07
Gender				-0.04
Step Two	-	-	0.06	$F_{2,40} = 2.37$, P=0.11
Yrs Diagnosed				0.09
Diab. Complications				**-0.34***

* p<0.05, ** p<0.01, *** p<0.001

At 9 month follow-up the number of diabetes complications at baseline was predictive of residualised change in HbA1c (see table 12.1). The greater the number of diabetes complications at baseline the greater the decrease in HbA1c between baseline and 9 months follow-up (see figure 12.1). In total the equation explained 6% of the variance in change in glycaemic control at 9 months.

Figure 12.1 Scatterplot of the Relationship Between Diabetes Complications at Baseline and HbA1c Residualised Change Scores at 9 Months Follow-Up



12.3 Prediction of Change in Behaviour following the UCL-DSMP

12.3.1 Diet

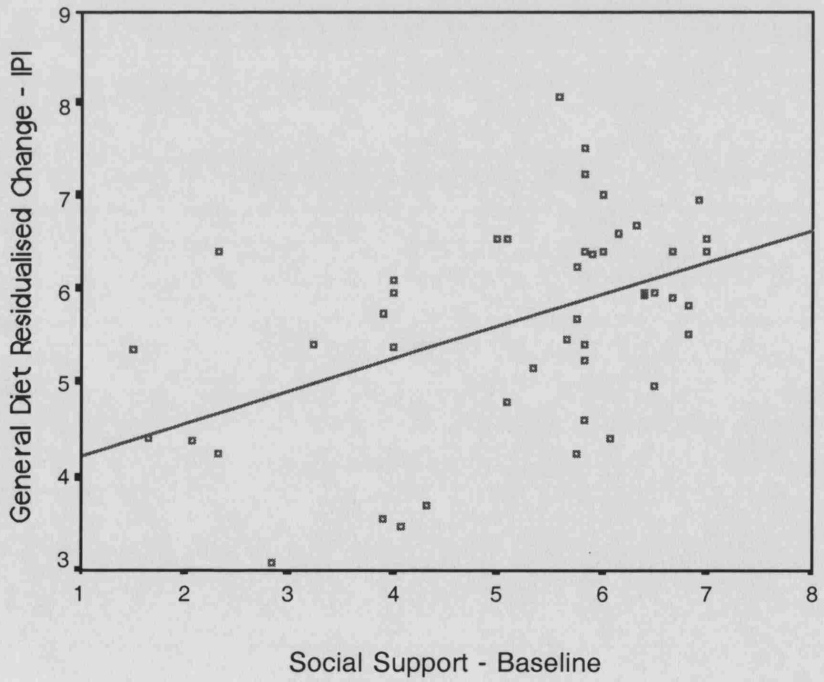
Table 12.2 shows the results of predictor analysis for general dietary behaviour at each follow-up assessment. Baseline levels of social support (total scores on the MSPSS) significantly predicted residualised change scores in general dietary behaviour at both IPI ($p<0.05$) and 9 month follow-up ($p<0.001$). Higher baseline scores of social support were associated with increases in general dietary behaviour (see figure 12.2). The relationship was strongest at 9 months follow-up with 27% of the variance in the dependent variable explained whilst only 12.6% of the total variance was explained by this at IPI.

Table 12.2 Prediction of Residualised Change in General Dietary Behaviour at IPI, 3 Months and 9 Months Follow-Up

	IPI		3 Month Follow-Up		9 Month Follow-Up	
Predictor Variables	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**
Step One	-0.01	$F_{3,30}$ = 0.83, P=0.48	0.00	$F_{3,36}$ = 1.00 P=0.40	0.02	$F_{3,38}$ = 1.27 P=0.30
Age		0.02		0.14		-0.22
Educ. Qual.		-0.14		-0.08		0.18
Gender		-0.01		0.09		0.04
Step Two	0.06	$F_{2,28}$ = 2.470, P=0.10	-0.05	$F_{2,34}$= 0.102, P=0.90	-0.01	$F_{2,36}$= 0.53, P=0.59
Yrs Diag		0.23		-0.02		-0.02
HbA1c		0.03		0.09		0.06
Step Three	0.19	**$F_{1,26}$=6.75 P<0.05**	0.15	**$F_{1,33}$= 9.110, P<0.01**	0.27	**$F_{1,35}$=14.86, P<0.001**
Soc. Sup.		**0.39***		-		**0.55*****
Depression		-		**-0.48****		-

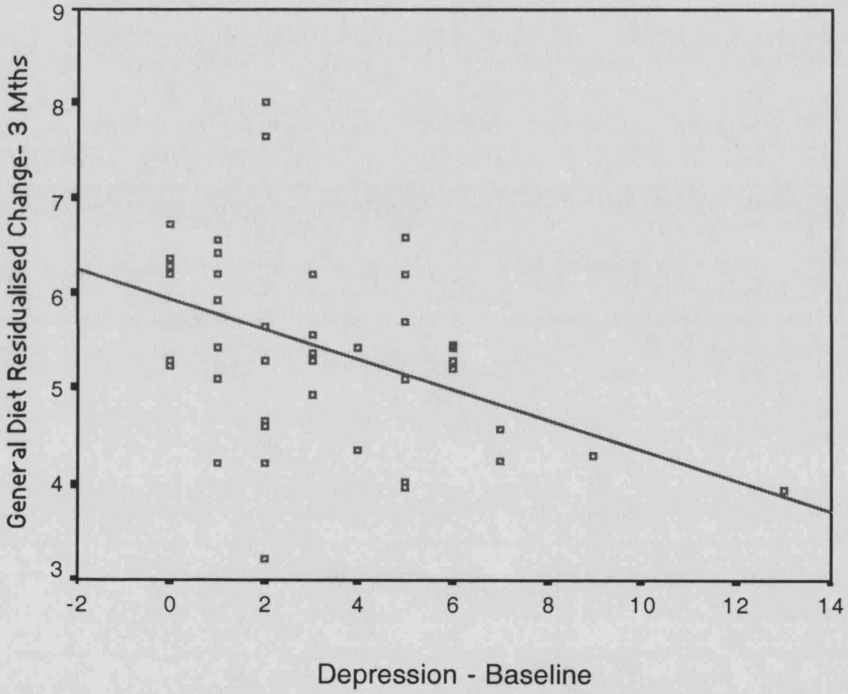
* p<0.05, ** p<0.01, *** p<0.001

Figure 12.2 Scatterplot of the Relationship Between Social Support at Baseline and General Diet Residualised Change Scores at IPI



Baseline depression was entered into the regression analysis at 3 months follow-up (see table 12.2). A negative relationship was found (see figure 12.3) such that lower baseline depression was associated with increase in general dietary residualised change scores at 3 months follow-up. All of the 15% variance explained by this equation was attributed to depression.

Figure 12.3 Scatterplot of the Relationship Between Depression at Baseline and General Diet Residualised Change Scores at 3 Months Follow-Up



No significant correlations were found between baseline variables and residualised change scores for fruit and vegetable consumption at either IPI or 9 month follow-up hence regression analyses were not conducted at these points. At 3 month follow-up the number of years diagnosed with diabetes predicted change in fruit and vegetable

consumption such that a shorter time since diagnosis was associated with increase in the frequency of fruit and vegetable consumption (see table 12.3). Together with baseline HbA1c number of years diagnosed with diabetes predicted 10% of the variance in change in fruit and vegetable consumption.

Table 12.3 Prediction of Residualised Change in Consumption of Fruit and Vegetables at IPI, 3 Months, 9 Months Follow-Up

	IPI		3 Month Follow-Up		9 Month Follow-Up	
Predictor Variables	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**
Step One *Age* *Educ. Qual.* *Gender*	-	-	0.03	$F_{3,40}$= 0.57, P=0.64 0.09 0.06 0.16	-	-
Step Two *Yrs Diag* *HbA1c*	-	-	0.10	**$F_{2,38}$= 3.94 P<0.05** **-0.38*** 0.29	-	-

** p<0.05, ** p<0.01, *** p<0.001*

Baseline levels of depression were significant predictors of change in fat consumption at IPI, 3 month and 9 month follow-up (see table 12.4). At IPI 33.6% of the variance in change in fat consumption was explained by the total model, with approximately 17% of the variance attributable solely to baseline depression. At 3 month follow-up approximately 15% of the variance was attributable to baseline depression whilst at 9 months follow-up this rose to 20%. At both 3 and 9 month follow-up demographic and clinical variables explained negligible amounts of variance in the dependent variable. The relationship between baseline depression and change in fat consumption was similar to that in figure 12.3. Lower baseline depression was associated with increase in frequency of appropriate fat consumption.

Table 12.4 Prediction of Residualised Change in Consumption of Fat at IPI, 3 Months and 9 Months Follow-Up

	IPI		3 Month Follow-Up		9 Month Follow-Up	
Predictor Variables	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**
Step One	0.07	$F_{3,36}$ = 1.93, P=0.14	-0.04	$F_{3,35}$= 0.50, P=0.68	-0.05	$F_{3,35}$ = 0.36, P=0.78
Age		0.12		-0.02		0.04
Educ. Qual.		0.06		-0.08		0.06
Gender		**0.34***		-0.07		-0.13
Step Two	0.17	$F_{2,34}$ = 3.20, P=0.05	0.01	$F_{2,33}$= 1.87 P=0.17	-0.05	$F_{2,33}$ = 1.03, P=0.37
Yrs Diag		0.11		0.09		0.13
HbA1c		-0.27		-0.18		**-0.35***
Step Three	0.34	**$F_{1,33}$ =9.58, P<0.004**	0.15	**$F_{1,32}$= 6.66, P<0.05**	0.20	**$F_{1,32}$ = 11.34, P<0.01**
Depression		**-.43****		**-0.42***		**-0.50****

** p<0.05, ** p<0.01, *** p<0.001*

At IPI gender was also identified as a significant predictor of change in fat consumption, post-hoc t-tests however did not demonstrate a significant difference between male and females on this variable. At 9 month follow-up HbA1c was identified as a significant predictor with higher HbA1c at baseline associated with greater increases in appropriate fat consumption. Although HbA1c was identified as a significant predictor of appropriate fat consumption at 9 months follow-up, when combined with years since diagnosed with diabetes, this step of the equation explained a negligible amount of variance.

12.3.2 Exercise

As shown in table 12.5 different predictors of change in exercise behaviour were identified at each follow-up assessment. At IPI RTC exercise behaviour positively predicted change in exercise such that individuals who reported being more willing to change their exercise behaviour at baseline demonstrated greater increase in exercise at IPI. RTC accounted for 17.5% of the variance in exercise residualised change scores

at IPI. Baseline self-efficacy for exercise was also significantly correlated with residualised change in exercise at IPI. It was not entered into the regression analysis however as both RTC exercise and self-efficacy were strongly correlated (r=0.509, p<0.001). Concerns over multi-collinearity meant only one of these variables could be entered into the equation. RTC for exercise was therefore selected as this showed the stronger relationship with residualised change in exercise behaviour (r=0.457, p<0.001 for RTC exercise, as compared to r=0.357, p<0.01 for exercise self-efficacy).

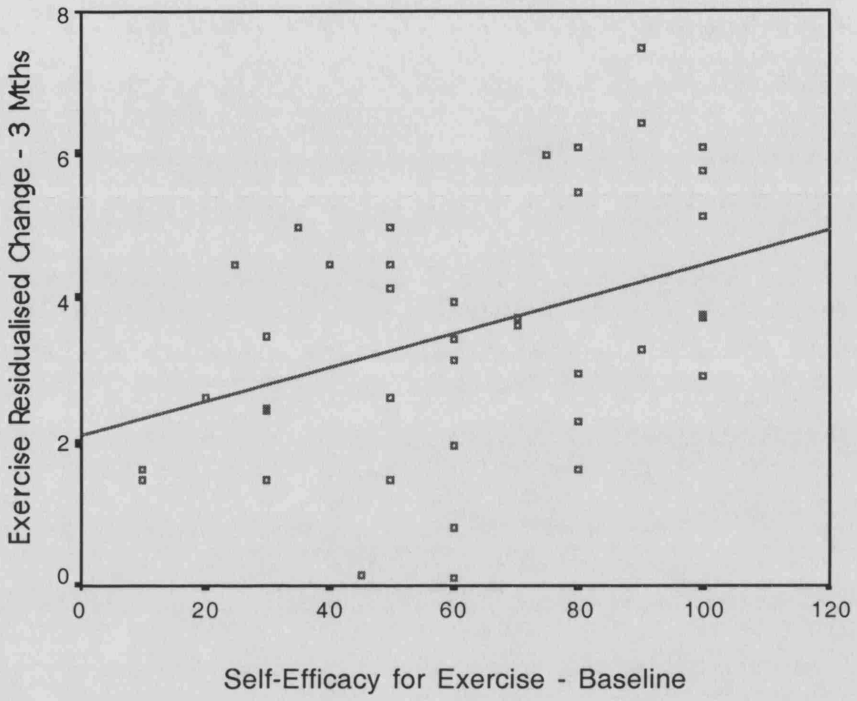
Table 12.5 Prediction of Residualised Change in Exercise at IPI, 3 Months and 9 Months Follow-Up

	Immediate Post-Intervention		**3 Month Follow-Up**		**9 Month Follow-Up**	
Variables	**Adj R^2**	**F Change** **Beta**	**Adj R^2**	**F Change** **Beta**	**Adj R^2**	**F Change** **Beta**
Step One	0.01	$F_{3,39}$ =1.19, P=0.33	0.00	$F_{3,37}$ = 1.04, P=0.39	0.06	$F_{3,37}$ = 1.89, P=0.15
Age		0.19		0.15		0.01
Educ. Qual.		-0.06		0.08		-0.06
Gender		-0.14		-0.13		-0.08
Step Two	-0.01	$F_{2,37}$ =0.57, P=0.57	-0.05	$F_{2,35}$ = 0.06, P=0.95	0.11	$F_{2,35}$ = 2.08, p=0.140
Yrs Diag		-0.140		-0.09		0.13
HbA1c		-0.04		0.00		0.24
Step Three	0.18	**$F_{1,36}$ =9.29 P<0.01**	0.11	**$F_{1,34}$ = 7.50, P<0.01**	0.19	**$F_{1,34}$ = 4.21, P<0.05**
RTC Exercise		**0.47****		-		-
SE Exercise		-		**0.43****		-
Knowledge		-		-		**-0.40***

* p<0.05, ** p<0.01, *** p<0.001; RTC- readiness to change, SE- Self-Efficacy,

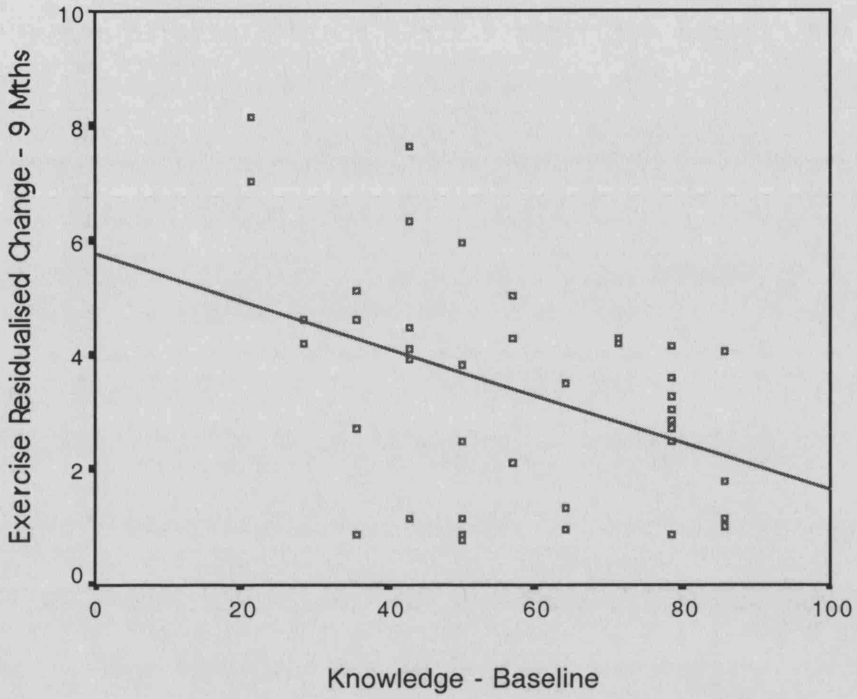
At 3 month follow-up, baseline RTC exercise no longer significantly correlated with residualised change in exercise and hence was not entered into the regression equation. Self-efficacy for exercise did however and explained 11% of the variance in change in exercise behaviour when entered into the equation. Higher self-efficacy at baseline was associated with greater increases in exercise at 3 months follow-up (see figure12.4).

Figure 12.4 Scatterplot of the Relationship Between Exercise Self-Efficacy at Baseline and Exercise Residualised Change Scores at 3 Months Follow-Up



Baseline knowledge levels were identified as significant predictors of change in exercise behaviour between baseline and 9 months follow-up. A negative relationship was seen such that lower knowledge at baseline was associated with increases in exercise behaviour at 9 months follow-up (see figure 12.5). In total this model explained approximately 19% of the variance in change in exercise behaviour. Approximately 6% was explained by demographic factors, a further 5% by clinical factors and a further 8% by knowledge at baseline. Due to significant correlations between knowledge levels and both age of participants ($p<0.01$) and educational level ($p<0.01$) at baseline, the possibility of multicollinearity of independent variables should be considered and the model treated with caution.

Figure 12.5 Scatterplot of the Relationship Between Knowledge at Baseline and Exercise Residualised Change Scores at 3 Months Follow-Up



12.3.3 Self Monitoring of Blood Glucose

At IPI residualised change scores for SMBG were significantly predicted by baseline scores of positive affect (see table 12.6). A negative relationship was seen such that lower positive affect at baseline was associated with increases in SMBG between baseline and IPI. In total the model explained 24% of the variance in change in SMBG. Eight percent of this was explained by demographic variables, with a further 6% by clinical variables and an additional 10% by positive affect. No variables at baseline were significantly correlated with residualised change scores for SMBG at 3 months follow-up hence regression analysis was not conducted for this follow-up.

Table 12.6 Prediction of Residualised Change in SMBG at IPI, 3 Months and 9 Months Follow-Up

	IPI		3 Month Follow-Up		9 Month Follow-Up	
Predictor Variables	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**
Step One	0.08	$F_{3,38}$=2.23,p=0.10	-	-	-0.07	$F_{3,39}$ = 0.02, p=0.100
Age		0.05				-0.03
Educ. Qual.		-0.21				-0.06
Gender		0.26				-0.12
Step Two	0.14	$F_{2,36}$=2.36,p=0.11	-	-	-0.05	$F_{2,37}$ = 1.45, p=0.25
Yrs Diag		0.22				**0.32***
HbA1c		0.25				0.07
Step Three	0.24	**$F_{1,35}$=5.58,p<0.05**	-	-	0.18	**$F_{1,36}$= 11.82, P<0.001**
Positive Affect		**-0.38***				**-**
SE Diet		**-**				**-0.52*****

* p<0.05, ** p<0.01, *** p<0.001; SE- self-efficacy

At 9 month follow-up residualised change in frequency of SMBG was significantly predicted by the number of years diagnosed with diabetes (p<0.05) and self-efficacy for diet (P<0.001). Although the number of years diagnosed with diabetes was identified in the regression analysis as being significantly associated with the dependent variable, when combined with HbA1c in step 2 of the regression equation a negligible amount of variance was explained. Baseline self-efficacy for diet explained 18% of the variance in the dependent variable. Self-efficacy for diet was negatively associated with change in SMBG hence lower dietary self-efficacy at baseline was associated with increased frequency of SMBG at 9 month follow-up.

12.4 Prediction of Change in Quality of Life following the UCL-DSMP

12.4.1 Diabetes Specific Quality of Life

Demographic variables did not predict residualised change scores for diabetes specific QoL at any follow-up. Clinical variables were not predictive at IPI or 3 months, however,

at 9 months follow-up the combination of years diagnosed with diabetes and HbA1c at baseline, explained 10% of the variance in the dependent variable, although neither were significant predictors when considered individually.

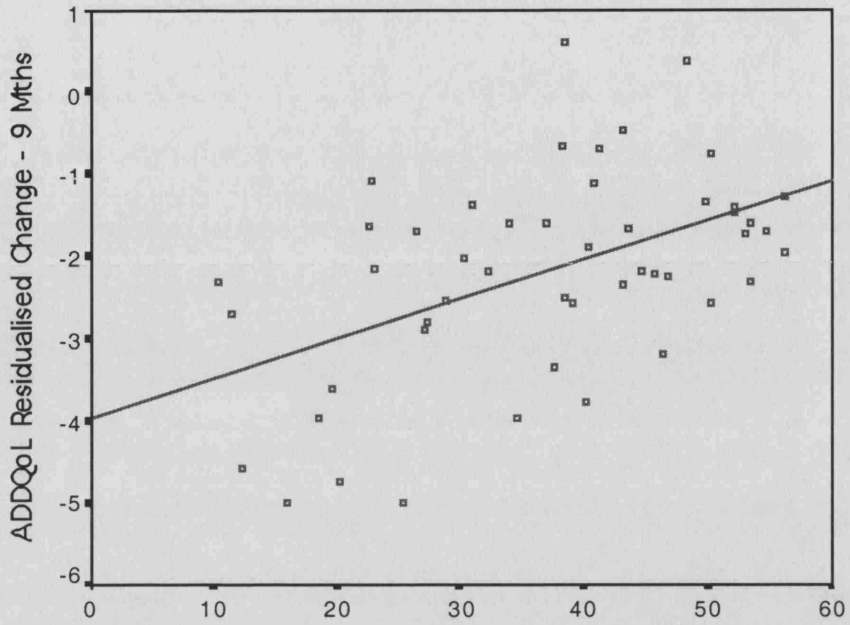
Table 12.7 Prediction of Residualised Change in Diabetes Specific Quality of Life at IPI, 3 Months and 9 Months Follow-Up

	Immediate Post-Intervention		**3 Month Follow-Up**		**9 Month Follow-Up**	
Predictor Variables	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**
Step One	-0.07	$F_{3,41}$ = 0.07, p=0.97			0.00	$F_{3,41}$ = 1.01, p=0.40
Age		0.00				-0.03
Educ. Qual.		0.06				0.11
Gender		0.08				-0.09
Step Two	-0.10	$F_{2,39}$ = 0.31, p=0.73			0.10	**$F_{2,39}$ = 3.28, p<0.05**
Yrs Diag		-0.00				-0.26
HbA1c		-0.03				0.04
Step Three	0.03	**$F_{1,38}$ = 6.40, p<0.05**			0.24	**$F_{1,38}$ = 7.94, p<0.01**
SF-36 PCS		**0.40***				**0.40****

* p<0.05, ** p<0.01, *** p<0.001; SF-36 PCS – Short form 36 physical composite score

At both IPI and 9 month follow-up baseline scores on the SF-36 PCS were significant predictors of change in the dependent variable. At IPI the amount of variance explained by the SF-36 PCS was only 3%, however at 9 month follow-up 14% of the variance was explained. This was in addition to the 10% explained by clinical variables. Figure 12.6 shows the relationship between baseline SF-36 PCS and change in diabetes specific QoL at 9 months follow-up. Higher baseline scores on the SF-36 PCS were associated with greater increases in diabetes specific QoL at both IPI and 9 months follow-up.

Figure 12.6 Scatterplot of the Relationship Between SF-36 PCS at Baseline and Diabetes Specific Quality of Life Residualised Change Scores at 9 Months Follow-Up



12.4.2 Generic Quality of Life

Diabetes specific QoL at baseline was a significant predictor of residualised change on the SF-36 PCS at IPI (see table 12.8). Better diabetes specific QoL at baseline was associated with greater increases on the SF-36 PCS, however the amount of variance explained was small (5.5%) and demographic and clinical variables did not contribute to explanation of the variance.

No significant correlations between baseline variables and residualised change scores on the SF-36 PCS were found at 3 or 9 months follow-up, hence regression analyses were not conducted at these periods.

Table 12.8 Prediction of Residualised Change in SF-36 PCS at IPI, 3 Months and 9 Months Follow-Up

	Immediate Post-Intervention		3 Month Follow-Up		9 Month Follow-Up	
Variables	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**
Step One	-0.04	$F_{3,41} = 0.51$, P=0.68	-	-	-	-
Age		0.03				
Educ. Qual.		0.13				
Gender		0.08				
Step Two	-0.05	$F_{239} = 0.69$, P=0.51	-	-	-	-
Yrs Diag		-0.00				
HbA1c		-0.08				
Step Three	0.06	**$F_{1,38} = 5.35$, P=0.03**	-	-	-	-
ADDQoL		**0.36***				

* p<0.05, ** p<0.01, *** p<0.001

As with the SF-36 PCS significant predictors of residualised change in the SF-36 MCS were only identified at IPI (see table 12.9).

Table 12.9 Prediction of Residualised Change in SF-36 MCS at IPI, 3 Months and 9 Months Follow-Up

	Immediate Post-Intervention		3 Month Follow-Up		9 Month Follow-Up	
Variables	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**
Step One	-0.05	$F_{3,41} = 0.30$, P=0.83	-	-	-	-
Age		-0.03				
Educ. Qual.		0.11				
Gender		-0.14				
Step Two	-0.01	$F_{239} = 0.09$, P=0.92	-	-	-	-
Yrs Diag		0.05				
HbA1c		-0.12				
Step Three	0.06	$F_{1,38} = 7.55$, P=0.01	-	-	-	-
fat		0.41**				

* p<0.05, ** p<0.01, *** p<0.001

Demographic and clinical variables did not explain any variance in residualised change in the SF-36 MCS between baseline and IPI, however consumption of fat at baseline explained approximately 6% of the variance. More frequent consumption of a low fat diet at baseline was associated with increases in QoL.

12.5 Prediction of Change in Psychological Well-Being Following the UCL-DSMP

12.5.1 Depression

Baseline variables were not significantly correlated with residualised change scores for depression at IPI or 9 months follow-up, hence regression analyses at these periods were not conducted. Baseline social support was predictive of residualised change in depression scores between baseline and 3 months follow-up (see table 12.10).

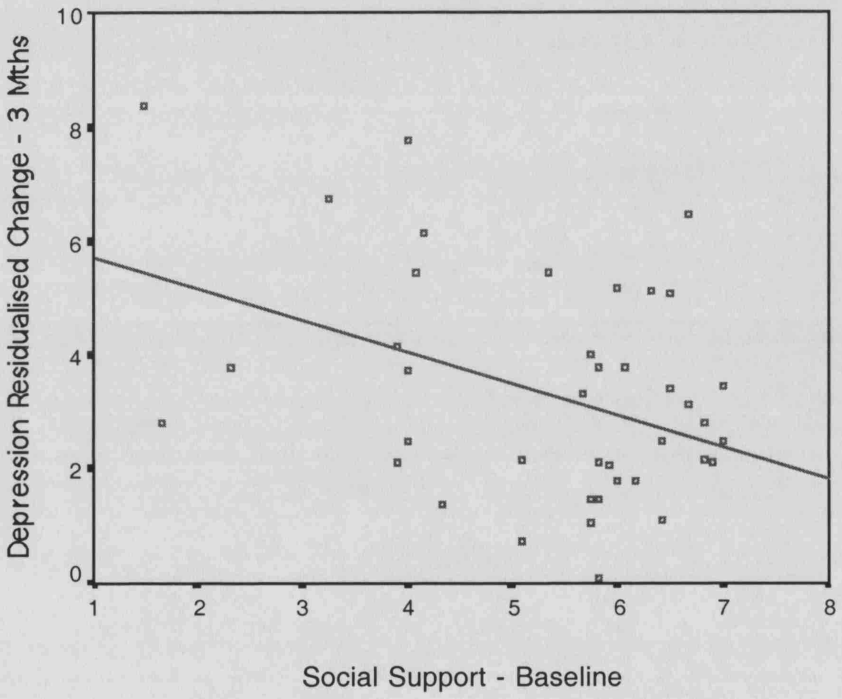
Table 12.10 Prediction of Residualised Change in Depression at IPI, 3 Months and 9 Months Follow-up

	IPI		3 Month Follow-Up		9 Month Follow-Up	
Predictor Variables	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**
Step One *Age* *Educ. Qual.* *Gender*	-	-	-0.05	$F_{3,33}$ = 0.47, P=0.71 -0.05 -0.21 0.16	-	-
Step Two *Yrs Diag* *HbA1c*	-	-	-0.02	$F_{2,31}$ = 1.50, P=0.24 -0.17 0.32	-	-
Step Three *SocSup*	-	-	0.23	**$F_{2,30}$= 10.79, P<0.01** **-0.52****	-	-

* p<0.05, ** p<0.01, *** p<0.001

In total the model predicted 23% of the variance in the dependent variable with this solely attributable to social support. A negative relationship was demonstrated such that individuals with higher social support at baseline had decreases in depression at 3 months follow-up (see figure 12.7).

Figure 12.7 Scatterplot of the Relationship Between Social Support at Baseline and Depression Residualised Change Scores at 3 Months Follow-Up



12.5.2 Anxiety

Significant correlations between baseline variables and residualised change in anxiety at IPI were not identified. At both 3 and 9 months follow-up however baseline HbA1c was predictive of residualised change in anxiety (see table 12.11). Higher baseline HbA1c levels were associated with increases in anxiety following the intervention.

Table 12.11 Prediction of Residualised Change in Anxiety at IPI, 3 Months and 9 Months Follow-Up

	IPI		3 Month Follow-Up		9 Month Follow-Up	
Predictor Variables	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**
Step One	-	-	-0.04	$F_{3,35}$ = 0.51, p=0.68	0.09	$F_{3,35}$ = 2.24, p=0.10
Age				-0.06		-0.15
Educ.Qual.				-0.28		**-0.43****
Gender				-0.02		0.20
Step Two	-	-	0.04	$F_{2,33}$= 2.40, p=0.11	0.24	**$F_{2,33}$ = 4.51, p=0.02**
Yrs Diag				-0.20		**-0.16**
HbA1c				**0.36***		**0.46****

* p<0.05, ** p<0.01, *** p<0.001

At 3 months follow-up the amount of variance explained by clinical factors was only 4%, at 9 months follow-up however clinical variables explained approximately 15% of the variance in the dependent variable. Change in anxiety at 9 months was additionally predicted by educational level at baseline and 9% of variance was attributable to demographic factors. Post-hoc univariate analysis to explore how change in anxiety was influenced by educational level did not however demonstrate significant differences between the groups.

12.5.3 Negative Affect

Demographic and clinical variables were not significant predictors of change in negative affect at any assessment following the SMI and explained either negligible or only small amounts of variance (see table 12.12).

Table 12.12 Prediction of Residualised Change in Negative Affect at IPI, 3 Months and 9 Months Follow-Up

	IPI		3 Month Follow-Up		9 Month Follow-Up	
Predictor Variables	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**
Step One	-0.02	$F_{3,35}$ = 0.78, p=0.51	0.02	$F_{3,35}$ = 1.27, P=0.30	0.04	$F_{3,37}$ = 1.57, P=0.21
Age		0.14		-0.30		-0.18
Educ. Qual.		**-0.30***		-0.27		-0.15
Gender		-0.09		0.07		0.18
Step Two	-0.01	$F_{2,34}$ = 1.19, p=0.32	-0.03	$F_{2,33}$ = 0.11, p=0.89	0.03	$F_{2,35}$ = 0.71, P=0.50
Yrs Diag		-0.04		0.00		0.02
HbA1c		0.22		0.05		0.08
Step Three	0.37	**$F_{2,32}$= 11.15, p<0.00 1**	0.15	**$F_{2,32}$ = 8.16, p<0.01**	0.15	**$F_{2,34}$ = 6.28, P<0.05**
Fat Cons.		**-0.45****		**-0.44****		-
Exercise		**0.37***		-		-
SF-36 PCS		-		-		**-0.39***

* p<0.05, ** p<0.01, *** p<0.001; SF36 PCS – short form 36 physical composite scale

At IPI residualised change in negative affect was predicted by both baseline levels of exercise and fat consumption. Higher exercise at baseline was associated with increases in negative affect. The converse was true for fat consumption where greater frequency of following a low fat diet was associated with decreases in negative affect (see figures 12.8 & 12.9). The addition of baseline fat consumption and exercise to the regression equation explained 37% of the variance in change in negative affect at IPI.

At 3 months follow-up residualised change in negative affect was again predicted by baseline fat consumption, but not exercise. Only 15% of variance in the dependent variable was explained by fat consumption in this equation.

Figure 12.8 Scatterplot of the Relationship Between Fat Consumption at Baseline and Negative Affect Residualised Change Scores at IPI

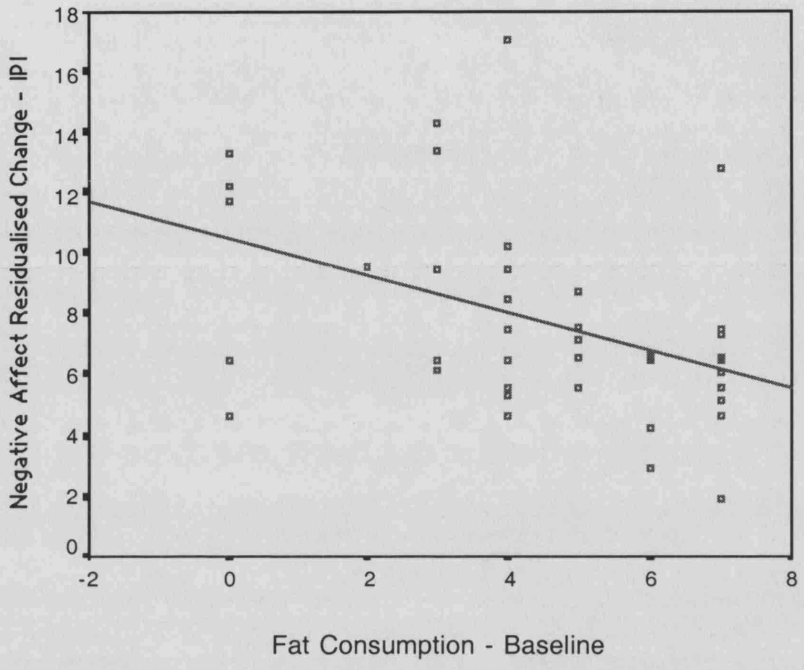
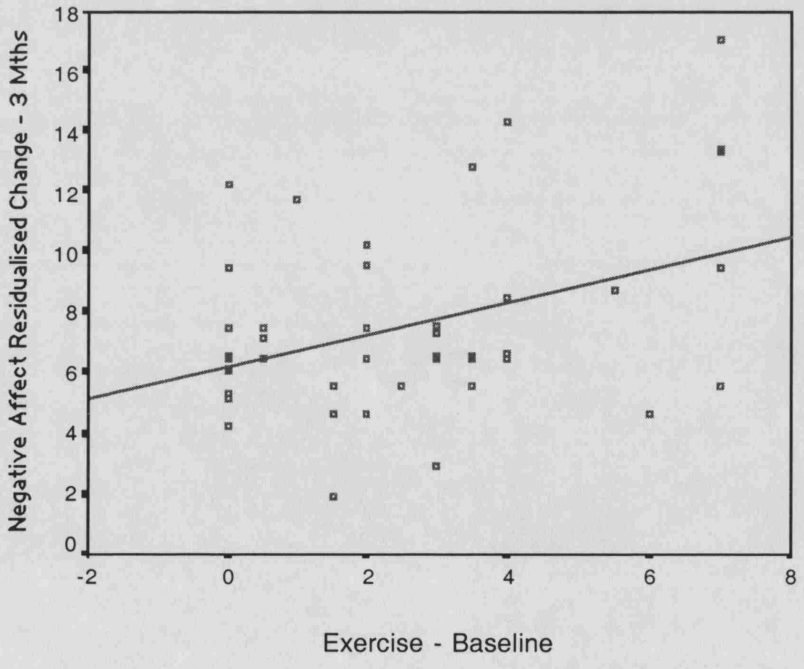


Figure 12.9 Scatterplot of the Relationship Between Exercise at Baseline and Negative Affect Residualised Change Scores at IPI



Baseline SF-36 PCS predicted residualised change in negative affect between baseline and 9 months follow-up (see table 12.12). A negative relationship was observed such that individuals with lower quality of life at baseline had greater increases in negative affect at 9 months follow-up. The total model explained 15.3% of the variance in change in negative affect with approximately 13% of this attributable to step 3 of the equation.

12.5.4 Positive Affect

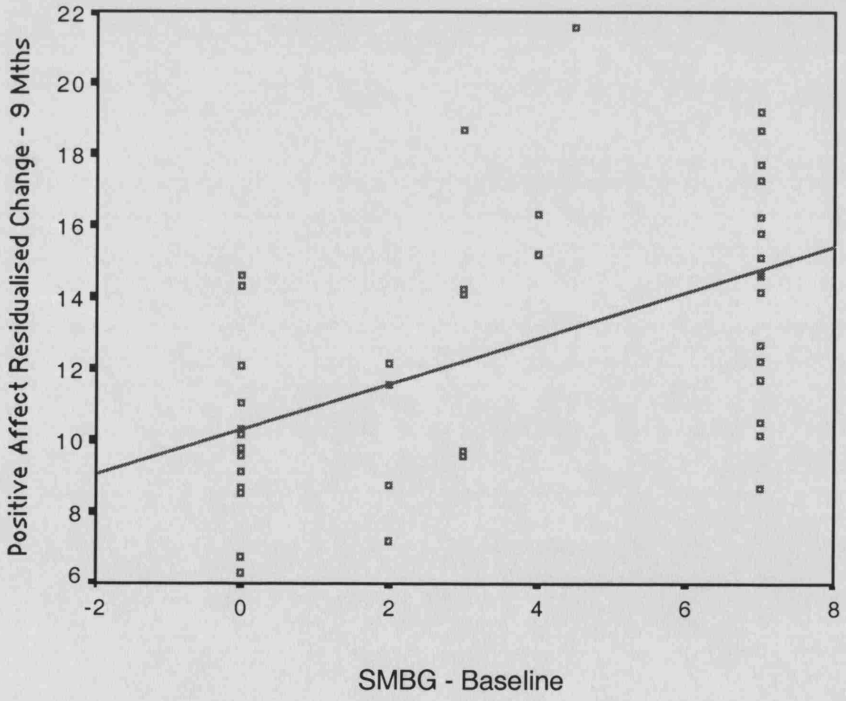
Baseline variables were not significantly correlated with residualised change in positive affect between baseline and IPI hence regression analysis was not conducted at this follow-up. At 3 months follow-up the number of years of diabetes diagnosis was found to be a significant predictor of residualised change in positive affect, however only 1% of variance in the dependent variable was explained by this regression equation (see table 12.13). Similarly, at 9 months follow-up although HbA1c was identified as a significant predictor it explained a negligible amount of variance in the dependent variable. In contrast the entry of two baseline variables (SMBG and RTC SMBG) on step 3 of the regression equation, explained 35% of the variance in residualised change in positive affect at 9 months follow-up. Higher frequency of SMBG and greater RTC SMBG at baseline was associated with increases in positive affect from baseline to 9 month follow-up. Examination of figure 12.10 however suggests that SMBG at baseline was not normally distributed hence this finding should be interpreted with caution.

Table 12.13 Prediction of Residualised Change in Positive Affect at IPI, 3 Months and 9 Months Follow-Up

	IPI		3 Month Follow-Up		9 Month Follow-Up	
Predictor Variables	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**	**Adj R^2**	**F Change Beta**
Step One	-	-	-.055	$F_{3,35} = 0.34$, p=0.79	-0.03	$F_{3,36} = 0.57$, p=0.64
Age				0.11		0.14
Educ. Qual.				0.08		0.09
Gender				-0.05		-0.01
Step Two	-	-	0.01	$F_{2,33} = 2.20$ p=0.13	-0.06	$F_{2,34} = 0.59$, p=0.56
Yrs Diag				**0.35***		0.03
HbA1c				-0.07		**-0.30***
Step Three	-	-	-	-	0.35	**$F_{2,34}$=11.75, P<0.01**
SMBG						**0.56*****
RTC SMBG						**0.31***

* p<0.05, ** p<0.01, *** p<0.001 RTC SMBG – Readiness to Change SMBG

Figure 12.10 Scatterplot of the Relationship Between SMBG at Baseline and Positive Affect Residualised Change Scores at 9 Months Follow-Up



A summary of the relationships found in the predictor analysis is presented in table 12.14.

Table 12.14 Summary Table of Predictors at Each Follow-Up

Residualised Change Outcome	**Predictor Variables – Amount explained by variable (amount explained by total equation)**		
	IPI	**3 Months FU**	**9 Months FU**
HbA1c	-	-	Complications 6.4% (6.4%)
General Diet	Social Support 12.6% (18.5%)	Depression 15% (15%)	Social Support 27.4% (27.4%)
Fruit	-	Years Diag. 10.1% (10.1%)	-
Fat	Gender 6.7% Depression 16.7% (33.6%)	Depression 15.3% (15.3%)	Depression 20% (20%)
Exercise	RTC Exercise 18% (18%)	Exercise Self-Efficacy 11% (11%)	Knowledge 7.5 (18.9%)
SMBG	Positive Affect 9.6 (24%)	-	Diet Self-Efficacy 18.7% (18.7%)
Diabetes QoL	SF-36 PCS 3% (3%)	-	SF-36 PCS 13.5% (23.6%)
SF-36 PCS	ADDQoL 5.5% (5.5%)	-	-
SF-36 MCS	Fat 5.9% (5.9%)	-	-
Depression	-	Social Support 22.8% (22.8%)	-
Anxiety	-	HbA1c 3.7% (3.7%)	Educ 8.9%, HbA1c 15.3% (24.2%)
Negative Affect	Fat, Exercise 37% (37%)	Fat 15.2% (15.2%)	PCS 12.8% (15.3%)
Positive Affect	-	Yrs Diag. 1.3% (1.3%)	HbA1c (0%) SMBG 35.2% (35.2%)

CHAPTER THIRTEEN: PREDICTING WHO BENEFITS FROM THE UCL-DSMP

13.1 Structure of the Chapter

This chapter discusses the results from chapter 12 which examined whether baseline individual differences predicted benefit from the UCL-DSMP. The extent that predictors were identified, and that these were consistent both across outcomes and at different follow-ups, is reported. The implications of the findings for selecting individuals to participate in SMIs is discussed.

As highlighted in chapter 12 prediction is of change scores hence where it is reported that higher baseline scores on a variable for example, predict improvement in the dependent variable, it should be recognised that the converse i.e. lower baseline scores predicting deterioration is also true. Where the amount of variance explained by a predictor variable was negligible i.e. 1 or 2% the findings are not commented upon.

13.2 Prediction of Intervention Efficacy

13.2.1 Demographic Variables as Predictors

Demographic characteristics including age, educational level and gender were forced into the first step of the regression analyses to examine the extent that these predicted outcome. In only two regression equations were demographic variables significant predictors of outcome. Gender was identified as a significant predictor of change in fat consumption at IPI, however on post-hoc analysis a significant relationship was not found, hence a difference between males and females on fat consumption was not seen. Likewise although educational level was a significant predictor of change in anxiety at 9 months follow-up, on post-hoc analysis there were no differences between educational levels and outcome. Demographic variables can therefore be considered poor predictors

of outcome following the current SMI. This finding is consistent with previous reviews of the literature (Norris *et al.,* 2002a, Padgett *et al.,* 1988).

13.2.2 Clinical Variables as Predictors

Clinical variables were not consistently strong predictors of benefit from the self-management programme, although more frequent relationships were seen than for demographic variables. Baseline HbA1c was the most consistent significant predictor of the clinical variables particularly with regard to change in psychological well-being. Higher HbA1c at baseline was predictive of an increase in anxiety at both 3 and 9 months follow-up and depression at 9 months follow-up. A similar finding was found by Lustman *et al.,* (1998b) who reported that higher baseline HbA1c was associated with lower remission of clinical depression following a cognitive behavioural intervention. Individuals with high HbA1c at baseline may therefore be at risk of poorer negative mood following SMIs than individuals with lower baseline HbA1c. The mechanism through which this occurs is not clear. One hypothesis is that SMIs may increase awareness of the seriousness of diabetes, which amongst individuals with higher HbA1c may impact negatively on mood. The relationship between perceived seriousness of diabetes and both higher negative affect and lower positive affect has been reported previously in non-intervention studies (Hampson *et al.,* 2000). In addition greater perceived seriousness of diabetes was associated with higher anxiety and negative affect at baseline in the current study. Although this hypothesis may appear plausible, change in beliefs about seriousness of diabetes were not predicted by baseline HbA1c, this could however have been due to factors such as lack of variance in change in beliefs about seriousness. It is therefore recommended that future intervention studies explore the relationship between high baseline HbA1c and change in mood post-intervention more fully.

The number of diabetes complications reported by an individual was identified as a significant predictor of change in HbA1c at 9 months follow-up. Individuals with a greater number of complications at baseline had greater decreases in HbA1c following the intervention. These individuals therefore appeared more sensitive to the intervention. Again the mechanism of this relationship is not clear. The number of diabetes complications at baseline was not predictive of change in self-management behaviours, which could have been hypothesised as the mechanism for change in HbA1c. It should be considered however that factors not measured in the current study may be important to understanding the mechanism. For example the taking of medication may have changed in individuals with high numbers of baseline complications, which may have mediated the change in HbA1c. As medication taking was not successfully measured in the current study this cannot be confirmed.

The number of years diagnosed was the third clinical variable to have predictive power. This predicted change in fruit and vegetable consumption. The amount of variance explained was notable (10.1%), however it was only at one time point and similar relationships were not seen with either of the other dietary measures. It would therefore be premature to suggest that individuals diagnosed for longer are less receptive to change in this behaviour.

13.2.3 Self-Management Behaviours as Predictors

Two self-management behaviours, exercise and fat consumption, were found to be predictors of change following the SMI. Exercise levels at baseline were predictive of change in negative affect between baseline and IPI. Lower levels of exercise at baseline were associated with decreases in negative affect IPI. The UCL-DSMP increased

exercise in the intervention group, and exercise has previously been shown to be associated with positive well-being (Salmon, 2000). It can be hypothesised that the prediction of change in negative affect, by low levels of exercise at baseline may have been mediated by increased exercise in this group. This was not however tested for in mediation analysis, and therefore can not be confirmed.

Fat consumption was also a significant predictor of change in negative affect between baseline and follow-up. Higher fat consumption at baseline was predictive of increases in negative affect at IPI and 3 months follow up. The self-management programme emphasised that a healthy diet should include avoidance of high fat foods. It is possible that the relationship above is due to individuals who had a high fat diet at baseline reducing their fat consumption. The relationship between fat consumption and mood is complex and evidence is often unclear, however it has been stated that fat consumption is associated with feelings of improved mood and is often used as a form of comfort when an individual is feeling low in mood (Christensen, 2001). If individuals low in mood reduce fat consumption, particularly without other forms of coping, it is conceivable that negative mood is increased. Such a phenomenon may have occurred in the current study. Although a speculative explanation, if this relationship were identified in future studies it would suggest that SMIs targeting individuals with high fat consumption and low mood at baseline, should address the relationship between mood and eating, and look in more detail at teaching alternative coping strategies for dealing with low mood if food consumption is not an option.

13.2.4 Quality of Life as a Predictor

Examination of QoL measures as predictors of change indicated that the SF-36 MCS was not a significant predictor for any outcome. The SF-36 PCS and the ADDQoL

however appeared inter-related such that higher baseline ADDQoL scores predicted increases in SF-36 PCS, and vice versa for change between baseline and IPI. In addition the SF-36 PCS remained a significant predictor of change in the ADDQoL between baseline and 9 months follow-up. These findings suggest that individuals with higher physical functioning or diabetes specific QoL at baseline were more sensitive to improvement in QoL following the intervention. The finding that change in QoL following an SMI is predicted by baseline QoL has been reported previously (Keers *et al.,* 2004), and gives support to the current finding.

13.2.5 Psychological Well-Being as a Predictor

Depression was a significant predictor of change in fat consumption between baseline and each follow-up, and general dietary behaviour between baseline and 3 months follow-up. Individuals with higher depression at baseline made less dietary change following the intervention, again highlighting the complexity of the relationship between mood and food consumption. An association between depression and poor self-management, in particular dietary behaviour, has been shown previously in the literature (Ciechanowski *et al.,* 2000). In a study by Hampson *et al.,* (2000) however depression was not found to be predictive of change in dietary outcomes between 9 and 12 months post a SMI. Although dietary behaviours changed initially following their intervention further change was not seen between the 9 and 12 months follow-ups. The Hampson study therefore addressed a slightly different issue from that in the current study i.e. does depression prospectively predict dietary behaviour when no immediate manipulation of behaviour is occurring. In contrast the question in the current study addressed whether levels of depression pre-intervention influenced the extent of change following the intervention. In the current study it would appear that individuals with higher levels of depression at baseline are less likely to change dietary behaviour

following the intervention. However from the findings of Hampson *et al.,* (2000) it may be suggested that depression would not be predictive of the maintenance of these findings following the intervention.

Negative affect and anxiety were not significant predictors of change following the intervention. Positive affect was a significant predictor of change in SMBG between baseline and IPI, with greater positive affect at baseline predicting less increase in SMBG. The relationship between positive affect and SMBG however appears complex, and possibly reciprocal, as more frequent SMBG at baseline was associated with increases in positive affect at 9 months follow-up. The non-normal distribution of SMBG at baseline and questions over the validity of the measure of positive affect in this sample (see discussion chapter 7) however mean these findings should be treated with caution.

13.2.6 Process Variables as Predictors

The final set of variables that were examined as predictors of change following the SMI were the process variables. There was little consistency in relationships with the exception of social support. Social support at baseline was a significant predictor of change in general dietary behaviour between baseline and IPI and 9 months follow-up, and change in depression between baseline and 3 months follow-up. The relationships were such that higher social support at baseline was associated with increases in diet and decreases in depression following the intervention. The association between social support and both self-care behaviours, particularly dietary behaviours (Gallant, 2003), and depression (Pouwer *et al.,* 2003, Penninx *et al.,* 1996) are well established in the literature. It is important that the current study indicates that social support predicts

benefit from a SMI as these findings lend support to the unfulfilled aim of the current study to try and increase social support skills amongst this population.

According to the TTM, used as one of the models to guide intervention development, it would be hypothesised that an individual's RTC a specific behaviour would be predictive of change in that behaviour. This was seen for exercise where individuals more ready to change behaviour at baseline showed greater change in actual behaviour at IPI. Similar relationships were not seen for diet and SMBG, however it must be considered that the single items used to measure RTC were only developed for this study and therefore had unknown reliability and validity as assessment tools. In addition SMBG was not performed by all individuals at baseline, hence responses to RTC SMBG at baseline may have been inaccurate due to misperceptions of what SMBG included.

Change in exercise behaviour between baseline and 3 months follow-up was also predicted by baseline self-efficacy for exercise, and baseline knowledge predicted change in exercise at 9 months follow-up. It could be suggested on the basis of the findings of the current study that individuals who have a high RTC will alter behaviour in the short term, but only those who were high in confidence initially, will have changed behaviour in the longer term.

SMBG at 9 months follow-up was also predicted by a baseline self-efficacy measure. Surprisingly it was dietary self-efficacy, as opposed to SMBG self-efficacy, that predicted SMBG. At baseline not all individuals conducted SMBG so did not report self-efficacy for this behaviour. As dietary and SMBG self-efficacy were correlated at baseline it may be that dietary self-efficacy reflected a proxy indicator of SMBG self-efficacy. Again it is of

note that baseline self-efficacy was only predictive of behaviour change in the longer term.

13.3 Implications and Conclusions of Predictor Analysis

The analysis of predictors in this study provides a fairly complex picture. In general results are in line with previous research suggesting that demographic and clinical variables have relatively low predictive power of who will benefit from a SMI (Sakardi & Rosenqvist, 2001; Glasgow *et al.,* 1997, Muchmore *et al.,* 1994). There is therefore little evidence to suggest that intervention efficacy will be improved by selecting sub-groups based on demographic or clinical variables.

Two individual differences were identified as important predictors in the current study. Firstly high levels of depression were a consistent predictor of lack of change in dietary behaviours. When change in diet is a key outcome of an SMI consideration may need to be given to selection of participants based on level of depression. Alternatively the content of interventions should include components likely to influence depression. Secondly social support was identified as an important predictor, particularly of general dietary behaviour, which commonly is a communal activity. This reinforces the importance of social support in explaining positive adaptation to chronic illness.

In several instances different predictors were identified for the same variable at IPI, 3 months and 9 months follow-up. This suggests that either individual differences, which predict initial change, are different to those which predict maintenance of change, or that there is little consistency in what predicts change in different outcomes at different time points.

Although of interest, the results of all predictor analyses in the current study should be treated with caution. The small sample size led to a marginal N for this type of analysis raising concerns over the power to detect 'real' effects. In addition given the large number of variables measured at baseline and multiple dependent variables there was potential for numerous analyses. This can lead to the risk of a type 1 error, i.e. detecting spurious relationships and hence reporting misleading findings. This was addressed by ensuring that only baseline variables significantly correlated with change in the dependent variable at $p<0.01$ were selected for entry into regression analysis. It may have been preferable however to take a more theoretically based approach to analysis with hypothesised predictors stated a priori and such an approach should be considered for future studies.

CHAPTER FOURTEEN: GENERAL DISCUSSION

14.1 Structure of the Chapter

This final chapter discusses the hypotheses stated in chapter 3 and examines the extent to which they were met. Other key findings of the study are discussed in relation to the state of self-management research in general and the diabetes literature. Limitations of the current study are presented before a final discussion of the implications of the current study for future research and clinical practice.

14.2 Testing of Hypothesis One: Individuals Attending a Self-Management Intervention Will Demonstrate Greater Improvement on Self-Management Behaviours, Glycaemic Control and Quality of Life than a Control Group.

The extent that this hypothesis was met was dependent on the particular outcome and the assessment period. All self-management behaviours were improved in the intervention group relative to the control group at IPI, and both exercise and SMBG were significantly better in the intervention group than controls at 3 and 9 months follow-up. The improvement in exercise and maintenance over time is particularly encouraging given that reviews of the literature have suggested variable effects of SMIs on exercise (Norris *et al.,* 2001, see also chapter 3, section 3.4.1.2). The maintenance of effects for exercise is in contrast with the lack of improvement of dietary behaviours in the intervention group relative to controls at 3 and 9 months follow-up. The possible reasons for this have been discussed in chapter 9.

The UCL-DSMP had a significant effect on diabetes specific QoL. An improvement in QoL in the intervention group relative to controls was seen at IPI and retained at 3 and 9 months follow-up.

The intervention did not however, have a significant effect on glycaemic control at either 3 or 9 months follow-up. If glycaemic control is considered to be the primary outcome of SMIs the lack of effect on this outcome could lead to the conclusion that the UCL-DSMP was inefficacious. There are however two important reasons why this is inappropriate. Firstly it can be argued that glycaemic control is only one of a number of important outcomes for individuals with type 2 diabetes. As highlighted by Barlow et al's (2002) definition of self-management (see chapter 2), and by the objectives of the diabetes National Service Framework (Department of Health, 2001) an important objective of SMIs is to aid individuals in making informed choices about their care with the objective of improving QoL. Relative to control group participants, individuals attending the UCL-DSMP had increased knowledge, changed their beliefs to those more supportive of a self-management framework, and had improved QoL, suggesting the UCL-DSMP was successful on a range of outcomes.

Secondly there is sometimes an assumption that glycaemic control is simply an indicator of successful self-management behaviours. It is often assumed that there is a one to one relationship between behaviour and glycaemic control, however this is perhaps too simplistic a view. Glycaemic control is influenced by many factors in addition to behaviour such as ill health, stress, etc. (Pickup & Williams, 1997). The complexity of the association between behaviour and clinical variables has been raised in recent systematic reviews and caution given against viewing these two factors as having a simple one to one relationship (Newman *et al.,* 2004).

Although the UCL-DSMP was efficacious on outcomes such as self-management behaviours, QoL and process variables (discussed under section 14.4) the effects were

most prominent at IPI with dissipation over time. This is characteristic of many SMIs in type 2 diabetes (Norris *et al.,* 2001; Clement, 1995). The current study aimed to address this issue by the inclusion of a booster session at 3 months post-intervention. The potential benefits of this booster session could not be defined as comparison was not made between individuals receiving and not receiving the session. It would appear however that it was not sufficient, given that initial benefits for changes in diet behaviour and illness perceptions were not retained in the longer term.

14.3 Testing of Hypothesis Two: Individuals Attending a Self-Management Intervention with Social Support Skills Training will Demonstrate Greater Improvement on Self-Management Behaviours, Glycaemic Control and Quality of Life than a Control Group but will Additionally Demonstrate Greater Efficacy than the Standard Intervention Group.

This hypothesis was based on the belief that social support is an important facilitator of behaviour change, hence the addition of social support skills training would lead to greater improvement on behaviours, clinical outcomes and QoL than in individuals receiving a self-management programme without this component. Unfortunately this hypothesis could not be tested as the arm of the trial evaluating the self-management programme with additional social support skills training was discontinued due to lack of uptake by participants. Although it can be concluded that within this population attendance at a self-management programme with a partner was not acceptable, inference as to the efficacy of social support skills training cannot be made. Future attempts to evaluate the role of social support skills training would need to take a different approach, e.g. addressing this without partners having to be present, or perhaps with younger populations.

14.4 Testing of Hypothesis Three: The Mechanism of Change Facilitating Improvement in Self-Management Behaviours from Baseline to Post-Intervention would be Mediated by Self-Efficacy and an Individual's Personal Models of Diabetes in Accordance with Social Cognitive Theory (SCT) and the Self-Regulation Model (SRM).

The current study was primarily based on two health psychology theories, SCT (Bandura, 1977, 1986) and SRM (Leventhal *et al.,* 1984), which were both suggested to explain change in self-management behaviours. The first question in considering this hypothesis was whether the intervention resulted in changes in the process variables defined by these theories, i.e. self-efficacy and personal models of diabetes. Self-efficacy for both exercise and SMBG was not different between groups at IPI, but both exercise self-efficacy and SMBG self-efficacy were greater in the intervention group than control group at 3 months follow-up and for SMBG at 9 months follow-up. In contrast individuals who had attended the UCL-DSMP had stronger beliefs in treatment effectiveness and personal control over blood glucose than individuals in the control group at IPI, but these effects were no longer significant at 3 and 9 months follow-ups. The UCL-DSMP therefore had some success in changing these process variables.

The role of these process variables in mediating a change in behaviour was examined in chapters 10 & 11, where it was concluded that the beliefs that comprise an individuals personal models were weak mediators of behaviour change. Evidence for self-efficacy as a mediator was stronger with change in both exercise and SMBG mediated by change in exercise self-efficacy and SMBG self-efficacy respectively. Therefore the current study could be taken to suggest that SCT has greater utility than the SRM for SMIs. The situation is more complex however as it is not clear that the UCL-DSMP was as effective at changing illness cognitions as it was at increasing self-efficacy.

Techniques for increasing self-efficacy have been defined in SCT and include vicarious learning, mastery through experimentation and practise of goal setting, and social persuasion. Unfortunately whilst the SRM defines the importance of illness beliefs for health outcomes, descriptions of the best methods to manipulate beliefs are not described.

14.5 Prediction of Intervention Efficacy

A specific hypothesis as to which variables at baseline would be predictive of intervention efficacy was not generated a priori. It was however an aim of the study to explore whether any individual differences at baseline could be identified as predictors of efficacy. In general, demographic and clinical variables were not strong predictors of outcome. This study therefore provided no support for using these variables as selection criteria for entry into a SMI. Some relationships of note were however identified. The finding that high HbA1c was predictive of poorer psychological well-being, particularly anxiety, following the SMI may be taken to suggest that the UCL-DSMP did not sufficiently address the emotional impact of coping with the implications of high HbA1c. Management of emotions was not an explicit focus of the current intervention. It may be however that this is a useful addition to the programme. Previous interventions in both diabetes (Lustman *et al.,* 1998; Peyrot & Rubin, 1999) and other illnesses (Keefe, Caldwell, Baucom, Salley, Robinson *et al.,* 1999; Evers, Kraaimatt, van Riel, de Jong, 2002) have targeted coping with emotions in SMIs and have shown some success. Inclusion of emotional coping strategies may also address the finding that higher depression at baseline was predictive of poorer efficacy particularly on dietary outcomes. It could be argued that individuals suffering from low mood may benefit from more specialised intervention and should be targeted separately, however in the current

study few individuals were categorised as having clinical depression or raised levels of depressive symptomatology.

Another baseline characteristic predictive of intervention efficacy was perceived social support. Individuals with greater perceived social support at baseline reported greater change in dietary behaviour following the intervention. This provides additional support for the importance of this variable. Recognising the importance of social support still leaves the question of the design of an appropriate intervention to manipulate this variable, and with particular reference to this study, one which attracts participants.

14.6 Evaluation of the UCL-DSMP from a Public Health Perspective

The current study can be seen to have produced some interesting results from a research perspective. The importance of SMIs is, however, not only in development and research evaluation, but also in translation of findings into clinical practice. Glasgow, (2003) has highlighted that there is often a gap between what is known about diabetes care and what is practised. To enhance translation of research into practice an acronym RE-AIM (Reach, Efficacy, Adoption, Implementation and Maintenance) has been developed (Glasgow, Wagner, Kaplan, Vinicor, Smith *et al.,* 1999; Glasgow, McKay, Piette, Reynolds, 2001). This aims to assist developers of SMIs in considering the broader aspects of SMIs, necessary for a true public health impact. Each of the RE-AIM components is described below, together with an evaluation of the extent that the UCL-DSMP addressed the component.

14.6.1 Reach

'Reach' is the extent that a programme penetrates the population that is targeted. It includes the participation rate and representativeness of participants. Details of the

participation rate and representativeness of the UCL-DSMP have been discussed in chapter 7. Participation rates were similar to those reported by other SMIs and the sample appeared representative of the population that was targeted. UCL-DSMP sessions were offered at different times of the day and evening, to increase accessibility to individuals who both worked or were retired or unemployed. However reach of the programme was decreased by being both hospital based and requiring regular attendance at sessions. Individuals who had difficulty travelling, were house-bound or could not attend regular sessions may have found the programme difficult to attend. There is no reason however for the programme to be hospital based in the future and given sufficient participants within a locality the programme could easily be held at community centres, general practices or even within occupational settings. Such changes would increase the reach of the UCL-DSMP.

14.6.2 Efficacy

Efficacy is the effect of the intervention if implemented as described in the protocol, and should include a range of outcomes including QoL. Efficacy of the UCL-DSMP has been demonstrated on self-management behaviours, QoL and a range of process variables and has been discussed in both chapter 9 and above, as has the problem of dissipation of effects in the longer term.

In evaluating efficacy the influence of study design should be considered. Traditionally RCTs are felt to be the 'gold standard' for trial evaluation based on the assumption that randomisation minimises differences between groups at baseline hence allowing any differences between groups at follow-up to be attributed to intervention effects. However Bradley, (1993, 1997) argues that this may not necessarily be the case if at the outset of the study participants have preferences for which intervention they receive. If a

preference is present but unfulfilled, i.e. by randomisation to the participant's less preferred group then this participant will be disappointed, or experience what has been termed 'resentful demoralization' (Cook & Campbell, 1979). It has been argued that participants agreeing to take part in a trial are therefore likely to have an interest in the new treatment particularly if this is the only way to receive the treatment (Bradley, 1993, 1997). Hence control group participants are likely to have higher rates of disappointment than those in the intervention group. Hence rather than control for differences between groups randomisation can in fact lead to baseline differences in some instances. The potential usefulness of preference designs has been reported in a number of areas (Tenhave, Coyne, Salzer & Katz, 2003; Fung & Lore, 2002; Feine, Awad & Lund, 1998)

Evaluation of efficacy in the current study used a part-randomised patient preference design, which can be considered a strength of the study. If simple randomisation between the attendance at the SMI, with or without a partner, had been used it can be hypothesised that i) uptake into the study would have been far lower and hence reach decreased, ii) it would have been far more complex to determine if it was the SMI per se, or as was proven, the requirement to attend with a partner that was unacceptable.

14.6.3 Adoption

Adoption is the extent to which health care settings will participate in and deliver the intervention. Conceptually this is similar to reach, with the distinction that adoption refers to uptake by health care settings, whilst reach refers to uptake by individual participants. As with reach, participation rates and representativeness of potential settings should be calculated. The extent to which the UCL-DSMP could be adopted into the health care system is currently unknown. It is a relatively intensive group intervention and these tend to be adopted less easily than more simple interventions e.g.

telephone interventions (Glasgow *et al.,* 2001). This however, does not necessarily need to be the case, as evidenced by the Chronic Disease Self-Management Programme within the UK. This is an example of a group intervention that is increasingly being adopted by Primary Care Trusts. The uptake of this, and other programmes of this type, is likely to be influenced by a range of factors, for example governmental support for the programme and increasing recognition of the need for a different approach to chronic illness management. The inclusion of the UCL-DSMP within the Diabetes UK examples of good practice for diabetes education (Naqib, 2002) is likely to facilitate the adoption of the current programme.

14.6.4 Implementation

Implementation is the extent to which the intervention is delivered as intended once in clinical practice. Implementation of a complex intervention is often more difficult than implementing simple interventions, however work on the UCL-DSMP took several steps to facilitate implementation, both within the current study and for future use of the programme. The first of these was the production of a detailed manual (see volume 2). The manual specified the broad content to be covered in each session and gave details of how to ask questions and probes to use. The use of a manual may raise concerns that the programme was prescriptive and did not allow the needs of individual participants to be addressed. However the manual was designed specifically to ensure individual's concerns and beliefs were elicited and addressed, whilst maintained within the agenda set by the facilitators. This allowed for an overall consistency of approach whilst recognising the individual differences of the participants.

The techniques used in the programme drew upon several health psychology theories and hence were relatively new to the nurses who were delivering the programme. The

manual therefore served the purpose of ensuring that techniques were consistently applied. In addition to the provision of a manual, all facilitators were trained in the theory upon which the programme was based and the techniques to be used. Such training of health care professionals is essential as the psychological techniques used in SMIs are often new to facilitators. The importance of training was highlighted by comments made by the main facilitator of the programme who reported that although she had always thought of herself as acting to facilitate behaviour change only by being trained in the new techniques did she recognise the difference in skills required (Jenkins, 2003).

Continued supervision of facilitators was also essential throughout the programme to ensure the intervention was being implemented as planned. This was done following each session by the thesis candidate. Quality control is an important aspect of SMI implementation as success is only likely to be achieved if the programme is implemented as intended.

14.6.5 Maintenance

Maintenance occurs both at the individual level, i.e. the long term effects of the intervention and the health care setting level, i.e the extent to which the programme is sustained. Maintenance of the UCL-DSMP at the individual level was dependent on outcome, with long-term effects for some variables e.g. exercise, SMBG and QoL but not others e.g. diet, personal models of diabetes, glycaemic control. The need for components to improve maintenance has been discussed previously. As the UCL-DSMP has not currently been adopted by the health care system it is not possible to comment on this further aspect of maintenance.

14.6.6 The Chronic Care Model

The RE-AIM framework aims to ensure that SMIs are not only efficacious but are designed appropriately to maximise their utility as part of the broader care plan for chronic illness. Management of all chronic illnesses including diabetes is being seen as a key challenge for the National Health Service, and any intervention that is currently developed should be useful to the care models that are currently being proposed. One model that has been suggested for use is the chronic care model, which originated within the USA (Wagner, 1998, Bodenheimer, Wagner & Grumbach, 2002; Wagner, 2004). This model describes the importance of six main components, i) community, ii) organisation of health care iii) supporting self-management iv) design of delivery systems, v) decision support, vi) clinical information systems (Lewis & Dixon 2004). The UCL-DSMP clearly falls within this model under support of self-management, however consideration needs to be given to how the current programme fits together with other SMIs in diabetes. Von Korff, Glasgow & Sharpe, (2002) have proposed a stepped approach to care for chronic illness where 'more complex and expensive interventions are given only when simpler and cheaper ones have been shown to be inadequate or inappropriate.' Although no cost analysis has been conducted on the current study the programme is relatively intensive compared to some other interventions in the UK (e.g. Clark & Hampson, 2001). The implications of this for future research and clinical practice are discussed below.

14.7 Limitations of the Current Study

The use of a patient preference design has been highlighted as a strength of the current study, however it should be considered that although preferences were taken into account this was only subsequent to randomisation to either immediate intervention or

delayed intervention. This may be considered a weakness of the study. It is possible that only individuals interested in a SMI were likely to consent to the study. There is evidence that this was the case as one of the main reasons given for not participating in the research trial was lack of interest in a SMI. This suggests that uptake into the study may have been greater if preference had included a choice between standard treatment and both interventions. With the design used, individuals in the control group may have been more disappointed in their allocation, than intervention participants, hence resulting in discrepancies between the groups at baseline. To try and address these potential differences two methods were used, firstly control group participants were told that they would be offered the SMI on completion of the trial. This was not only done with a view to decreasing disappointment in the control group but also from an ethical stand point, as it was believed that self-management is beneficial to individuals with diabetes. Secondly analysis of efficacy controlled for potential differences between groups at baseline using analysis of covariance with baseline scores of the dependent variable as the covariate.

A preferable design may have been to use a full preference trial where participants choose between standard treatment, self-management alone or self-management with partner. Although there may be differences between groups at baseline these would have the benefit of being explicit and if measured at baseline may give important information about whom SMIs could most usefully be targeted at. This design would also have eliminated another of the methodological weaknesses of the current study – method of randomisation. In the current study the method used was alternate allocation. This method does not adhere to allocation concealment and is therefore considered open to manipulation. In fact the need for manipulation of intervention allocation was the reason for selection of this method. Due to time pressures in which the trial had to be

conducted (design, conduction and evaluation within 3 years), and a lower number of eligible participants than expected, manipulation of randomisation was sometimes necessary to ensure that sufficient participants took part in any one intervention group. If this had not occurred some groups would have had to run with only 3-4 participants per group, this would have undermined the design of the programme which was based on a target of 6-8 participants per group to ensure utilisation of the group process could occur. Although the randomisation method was less than ideal there were no significant differences between groups at baseline and the analysis used was robust enough to account for any possible differences between groups.

A second weakness of the current study was reliance on self-report measures of behaviour. It can be argued that the study would have been enhanced by inclusion of objective measures such as blood lipid levels, inclusion of accelerometer/ pedometer readings, downloading of SMBG readings etc. Although objective measures add strength to the findings from self-report measures, the measure selected to assess behaviour (revised SDSCA scale) had good psychometric properties and had previously shown association with other measures of behaviour (Toobert *et al.,* 2000). The reason for not including objective measures of behaviour was again practical and due to limited resources. There was also an awareness that the assessment protocol of participants was intensive and hence a reluctance to add additional or repetitive assessments.

The final sample size was slightly below that required in the original power analysis, hence limiting the ability of the study to detect an intervention effect. Insufficient power has been a weakness of previous studies and therefore it was disappointing that the current study did not have a larger sample size. Recruitment was primarily limited by the inclusion criteria of microalbuminuria or proteinuria. Less participants than originally

expected had this diagnosis and fulfilled the other inclusion/exclusion criteria. In retrospect it may have been preferable to make the inclusion criteria as broad as possible, for example any individual with type 2 diabetes diagnosed for greater than 6 months. This would have had the benefit of both making recruitment into the study easier and also making the results more generalisable to the type 2 population. Alternativeiy to maximise the chance of finding a significant effect on glycaemic control only participants with type 2 diabetes and poorly controlled blood glucose e.g. HbA1c >8.0, could have been included. Although the latter may increase the probability of detecting an intervention effect on glycaemic control this approach can be seen to imply that the primary effect of self-management is to improve clinical outcomes. Although the importance of HbA1c is recognised, SMIs also aim to increase an individual's perception of control over their diabetes, change behaviours and improve QoL as equally important outcomes.

A criticism that may be levelled at the current study is the statistical analysis conducted, and in particular not using an intention to treat methodology. The Cochrane Collaboration include intention to treat methodology as an indicator of quality when conducting systematic reviews of health care interventions, and this design is recommended by the CONSORT statement (Moher, Schulz & Altman, 2001). Intention to treat methodology however addresses the effectiveness rather than efficacy of the intervention. Efficacy can be understood to assess whether under ideal circumstances the intervention works, whilst effectiveness addresses whether there are overall benefits of an intervention for a population, taking into account the fact that it is likely that not all individuals initially starting use of the intervention will continue to attend. In the current study it was believed that efficacy of an intervention should be addressed before effectiveness, hence analysis was conducted with only those individuals who attended

and completed the programme. As sufficient power is essential to demonstrations of efficacy and this study was somewhat limited in the number of participants who completed each follow-up, analysis of efficacy was conducted at each time point in preference to using a repeated measures design. Effectiveness was not reported in the current study as this was not the a priori research question however an intention to treat analysis has been conducted and published in the scientific literature (see appendix 6) and reports similar findings to those presented in this thesis.

14.8 Implications of the Current Study for Future Research and Clinical Practice

The weaknesses together with the strengths of the current study can lead to important recommendations for future research and clinical practice. From a research perspective the study would benefit from being replicated with larger numbers of participants, not limited to those with microalbumniuria or proteinuria, over longer follow-up periods and with more objective outcome measures of behaviour. The inclusion of other assessments such as cost-effectiveness should also be considered, although as noted by Loveman *et al.,* (2003) this can be difficult for SMIs.

An issue related to further development of both the UCL-DSMP and other diabetes SMIs is how to ensure maintenance of intervention effects over time. A more intensive protocol of booster sessions may be required than the single session that was offered in the current study. Work by Trento *et al.,* (2004) suggests that ongoing group sessions can be beneficial, and they have demonstrated significant benefits for individuals receiving regular 3 monthly sessions of up to 5 years relative to individuals receiving routine care. This or other approaches, e.g. more concentration on relapse prevention, need to be considered given the efficacy of many SMIs in the short-term but poor maintenance in the longer term.

Prediction analysis suggested that the UCL-DSMP may benefit from greater inclusion of techniques to address coping with the emotional impact of diabetes. This would be a useful addition to the programme in future development. Predictor analysis also emphasised the importance of social support training and highlighted that although not successful in the current study future studies should aim to manipulate this variable.

The conduction of mediation analysis in the current study highlighted the need for further research in this area. It is clear that not all mediators of behaviour change were identified in the current study. The mediators selected however were based on theoretical constructs with evidence of a relationship to behaviour change. It may be that health psychology theory is currently at a stage where other variables that may facilitate behaviour change have not been identified and operationalised.

As raised in chapter eleven a limitation within the field of health psychology and SMIs is how to manipulate the constructs that are defined in health psychology theories e.g. illness cognitions. Advancement of the field may need to concentrate more on interventions focussed initially at change in theoretical constructs, before complex interventions with a variety of theoretical constructs are developed. As suggested by Baronowski *et al.,* (2001) development of SMIs may best be served by a more staged approach than currently occurs. The important stages in development of behaviour change interventions are i) identification of theoretical factors associated with behaviour, ii) design of interventions to optimally change each of these theoretical factors, iii) the combination of different mediators to maximally improve behaviour in a complex self-management intervention. Further research using such an approach may be fruitful for the development of SMIs in type 2 diabetes.

Change in patient variables can be hypothesised to mediate intervention outcomes however both participant and other external characteristics may additionally moderate intervention effects. Moderator effects were not examined in the current study as a priori hypothesis were not stated relating to moderating effects, and there was concern about over analysis of the data. It can be hypothesised however that factors such as facilitator skill, group cohesiveness etc. could influence the efficacy of the intervention. Facilitator skill is particularly important and as reported was addressed in the current study by both training of facilitators before the study and ongoing supervision. It is an inherent problem of such interventions that when skills are new to a facilitator learning is likely to occur with practice. The MRC have recommended that to avoid such learning occurring during evaluation of a study an exploratory phase where the facilitator practises skills and the intervention is evaluated should occur (Medical Research Council, 2000). This stage could be seen as a feasibility study and could not only address training of facilitators but also factors such as development of intervention content, piloting of outcome assessments etc. The current study held one pilot session however this may have been insufficient to address all the needs of intervention development and skill development of facilitators. Longer periods of perhaps feasibility, intervention development and piloting may be more realistic before an expensive full trial is conducted.

Issues such as the training of health care professionals in the skills necessary for SMIs and quality control have important implications for the clinical implementation of SMIs. Barlow *et al.,* (2002) reported that a range of individuals deliver SMIs including some lay tutors but more commonly health care professionals. The health care professionals that deliver such interventions were diverse with eleven different professional groups being

represented. The extent that all of these groups will have received skills in behaviour change as part of their original training is unclear. The efficacy of SMIs is however dependent on correct delivery, hence it is essential that studies of all SMIs should describe not only the content of their intervention but also the training undergone by all facilitators. This was rarely done in the studies reviewed in chapter 3. In addition even when trained in the skills necessary for delivery of an SMI it is important to assess the extent to which these are applied over time. Techniques for doing this could include having an observer attend some sessions or having sessions videoed. The implementation of skills would then need to be compared to a quality framework. To the authors knowledge no such framework is currently available for SMIs in type 2 diabetes, however this is an important area for development if SMIs are to be used increasingly in clinical practice.

Another implication for clinical practice of the current study is how to integrate this SMI and other SMIs in type 2 diabetes within clinical practice. As suggested by Von Korff *et al.,* (2002) a stepped approach may be most useful, with individuals receiving basic interventions before attending a complex intervention such as that presented. Currently SMIs tend to be evaluated exclusively however consideration should also be given to the combination of different SMIs within clinical practice. For example it could be hypothesised that individuals attending the UCL-DSMP, but then receiving follow-up intervention where self-management behaviours are addressed in brief, 20 minute interventions at each clinic appointment (see Clark & Hampson, 2001 for full description), will receive greater benefit and more long term maintenance than attending either of these interventions alone. These different approaches are important to explore to ensure that self-management in type 2 diabetes continues to be optimised.

REFERENCES

Abate, N. & Chandalia, M. (2003) The Impact of Ethnicity on Type 2 Diabetes. *Journal of Diabetes and its Complications*, 17: 39-58.

Adler, A.I, Stratton, I.M., Neil, H.A.W., Yudkin, J.S., Matthews, D.R., Cull, C.A., Wright, A.D., Turner, R.C. & Holman, R.R. (2000). Association of Systolic Blood Pressure with Macrovascular and Microvascular Complications of Type 2 Diabetes (UKPDS 36): Prospective Observational Study. *British Medical Journal*. 321: 412-419.

Agurs-Collins, T. D., Kumanyika, S. K., Have, T. R., Ten S. & Adams-Campbell, L. L. (1997) A Randomized Controlled Trial of Weight Reduction and Exercise for Diabetes Management in Older African-American Subjects. *Diabetes Care*. 210, 9: 1503-1511.

Ahroni, J.H. & Boyko, E.J. (2000). Responsiveness of the SF-36 among Veterans with Diabetes Mellitus. *Journal of Diabetes and Its Complications*. 14: 31-39.

Aiken, L.S. & West, S.G. (1991) *Multiple Regression: Testing and Interpreting Interactions*. Newbury Park, CA: Sage Publications.

Aikens, J. E., Kiolbasa, T. A., Sobel, R. (1997) Psychological Predictors of Glycemic Change with Relaxation Training in Non-Insulin-Dependent Diabetes Mellitus. *Psychotherapy and Psychosomatics*. 66: 302-306.

Ajzen, I. (1985) From Intentions to Action: A Theory of Planned Behavior. In Kuhl, J. & Beckman, J. (Eds) *Action Control: From Cognitions to Behaviours*. New York, Springer: 11-39

Ajzen, I. (1991) The Theory of Planned Behavior *Organizational Behaviour and Human Decision Processes*, 50: 179-211.

Alberti, G., Zimmet, P., Shaw, J., Bloomgarden, Z., Kaufman, F. & Silink, M. (2004) Type 2 Diabetes in the Young: The Evolving Epidemic. The International Diabetes Federation Consensus Workshop. *Diabetes Care*, 27: 1798-1811.

Alexander, C,M. (2003) The Coming of Age of the Metabolic Syndrome. *Diabetes Care*, 26: 3180-3183

Aljasem, L.I., Peyrot, M., Wissow, L. & Rubin (2001) Barriers, Efficacy and Self-Care in Type 2 Diabetes. *Diabetes Educator*, 27: 393-404.

American Diabetes Association (1997) Diabetic Nephropathy. *Diabetes Care*, 20, S1: S24-S27.

American Diabetes Association (1998). Diabetes Mellitus and Exercise. *Diabetes Care*, 21,S1: S40-S44.

American Diabetes Association (2002) Management of Dyslipidemia in Adults with Diabetes. *Diabetes Care*, 25, S1: S74-S77.

American Diabetes Association (2002). Standards of Medical Care for Patients with Diabetes Mellitus. *Diabetes Care*, 26, S1: S33-S50.

American Diabetes Association. (2003). Evidence-Based Nutrition Principles and Recommendations for the Treatment and Prevention of Diabetes and Related Complications. *Diabetes Care.* 26, S1: 51-61.

Amos, A.F., McCarty D.J., Zimmet, P. (1997) The Rising Global Burden of Diabetes and its Complications: Estimates and Projections to the Year 2010. *Diabetic Medicine*, 14: S7-S85.

Anderson, R. M. (1995) Patient Empowerment and the Traditional Medical Model: A case of irreconcilable differences? *Diabetes Care.* 18, 3: 412-415.

Anderson, R.J., Freedland, K.E., Clouse, R.E. & Lustman, P.J. (2001). The Prevalence of Co-morbid Depression in Adults with Diabetes. A Meta-Analysis. *Diabetes Care.* 24, 6: 1069-1078.

Anderson, R.M., Funnell, M.M., Fitzgerald, J.T. & Marrero D.G. (2000) The Diabetes Empowerment Scale: A Measure of Psychosocial Self-Efficacy. *Diabetes Care*, 23: 739-743.

Anderson, R.M., Funnell, M.M., Butler, P.M., Arnold, M.S., Fitzgerald, J.T. & Feste, C.C. (1995) Patient Empowerment: Results of a Randomized Controlled Trial. *Diabetes Care*, 18: 943:949.

Anderson-Loftin, W., Barnett, S., Sullivan, P., Bunn, P. S., Tavakoli, (2002) A. Culturally Competent Dietary Education for Southern Rural African Americans with Diabetes. *Diabetes Educator*, 28: 245-257.

Arauz-Pacheco, C., Parrott, M.A. & Raskin, P. (2002) The Treatment of Hypertension in Adult Patients with Diabetes. *Diabetes Care*, 25: 134-147.

Arroyo, C., Hu, F.B., Ryan, L.M., Kawachi, I., Colditz, G.A., Speizer, F.E., Manson, J. (2004). Depressive Symptoms and Risk of Type 2 Diabetes in Women. *Diabetes Care*. 27, 1: 129-133.

Ary, D.V., Toobert, D., Wilson, W., Glasgow, R.E. (1986) Patient Perspective on Factors Contributing to Nonadherence to Diabetes Regimen. *Diabetes Care*. 9, 2; 168-172.

Aucott, L., Poobalan, A., Smith, W.C., Avenell, A., Jung, R., Broom, J. & Grant, M. (2004). Weight Loss in Obese Diabetic and Non-Diabetic Individuals and Long-Term Diabetes Outcomes – A Systematic Review. *Diabetes, Obesity and Metabolism*, 6: 85-94.

Audit Commission (2000) Testing Times: A Review of Diabetes Services in England and Wales. National Report, London.

Bandura, A (1986) *Social Foundations of Thought and Action.* Englewood Cliffs, NJ: Prentice Hall.

Bandura, A. (1977) Self-Efficacy: Toward a Unifying Theory of Behaviour Change. *Psychological Review,* 84: 191-215

Bandura, A. (1997) *Self-Efficacy: The Exercise of Control.* New York: Freeman.

Bandura, A. (2000) Health Promotion from the Perspective of Social Cognitive Theory. In Abraham, C. & Norman, P. (Eds) *Understanding & Changing Health Behaviour: From Health Beliefs to Self-Regulation*: 299-399. Amsterdam, Netherlands, Harwood.

Baranowski, T., Anderson, C. & Carmack, C. (1998) Mediating Variable Framework in Physical Activity Interventions: How Are We Doing? How Might We Do Better? *American Journal of Preventive Medicine*, 15: 266-297.

Barlow, J., Wright, C., Sheasby, J., Turner, A. & Hainsworth, J. (2002). Self-Management Approaches for People with Chronic Conditions: A Review. *Patient Education and Counseling*, 48: 177-187.

Baron, R.M. & Kenny, D.A. (1986) The Moderator-Mediator Variable Distinction in Social Psychological Research: Conceptual, Strategic, and Statistical Considerations. *Journal of Personality and Social Psychology*, 51: 1173-1182.

Baroni, M.G., Leslie, D., Pozzilli, P. & Bozzetti, R. (2000) Genetics of Diabetes: Unravelling the Complexities. In Betteridge, J. (Ed) *Diabetes Current Perspectives.* Martin Dunitz, London.

Barrera Jr., M., Glasgow, R. E., McKay, H. G., Boles, S. M., Feil, E. G. (2002) Do Internet-Based Support Interventions Change Perceptions of Social Support? An Experimental Trial of Approaches for Supporting Diabetes Self-Management. *American Journal of Community Psychology*, 30: 637-654.

Basa, R. B. and McLeod, B. (1995) Evaluation of a Diabetes Specialty Centre: Structure, Process and Outcome. *Patient Education and Counseling.* 25: 23-29.

Beck, A.T., Ward, C.H., Mendelson, M. Mock, J. & Erbaugh, J. (1961) An Inventory for Measuring Depression. *Archives of General Psychiatry,* 4, 561-571.

Becker, M.H. (1974). The Health Belief Model and Sick Role Behavior. *Health Education Monographs.* 2: 409-419.

Berkman, J. & Syme, S.L. (1979) Social Networks, Host Resistance, and Mortality: A Nine Year Follow-Up Study of Alameda County Residents. *American Journal of Epidemiology.* 109: 186-204.

Bernbaum, M., Albert, S. G., Brusca, S., Drimmer, A., Duckro, P. N., Cohen, J. D., Trindade, M. C., Silverberg, A. B. (1989) A Model Clinical Program for Patients with Diabetes and Vision Impairment. *The Diabetes Educator.* 15, 4: 325-330.

Bjorsness, D.K., Kerzowski, P.A., Harwell, T.S., McDowall, J.M., Butcher, M.K., Helgerson, S.D., Gohdes, D. (2003). Self-Blood Glucose Monitoring Practices. *Diabetes Care.* 26, 12: 3353-3354.

Black, S.A., Markides, K.S., Ray, L.A. (2003). Depression Predicts Increased Incidence of Adverse Health Outcomes in Older Mexican Americans with Type 2 Diabetes. *Diabetes Care.* 26: 2822-2828.

Blair, S.N., Kohl, H.W., Barlow, C.E., Paffenbarger, R.S., Gibbons, L.W., Macera, C.A. (1995). Changes in Physical Fitness and All Cause Mortality. *JAMA*, 273: 1093-1098.

Blonk, M. C., Jacobs, M. A. J. M., Biesheuvel, E. H. E., Weeda-Mannak, W. L., Henine, R. J. (1993) Influences on Weight Loss in "Type 2 Diabetic Patients: Little Long-Term Benefit from Group Behaviour Therapy and Exercise Training. *Diabetic Medicine*, 11: 449-457.

Bodenheimer, T., Wagner, E.H., Grumbach, K. (2002). Improving Primary Care for Patients with Chronic Illness. *JAMA.* 288, 14: 1775-1779.

Boehm, S., Schlenk, E. A., Raleigh, E., and Ronis, D. (1993) Behavioural Analysis and

Behavioural Strategies to Improve Self-Management of Type II Diabetes. *Clinical Nursing Research.* 2,3:327-344.

Boule, N.G., Haddad, E., Kenny, G.P., Wells, G.A., Sigal, R.J. (2001). Effects of Exercise on Glycemic Control and Body Mass in Type 2 Diabetes Mellitus. A Meta-Analysis of Controlled Clinical Trials. *JAMA.* 286, 10: 1218-1227.

Boyer, J.G., & Earp, J.A. (1997) The Development of an Instrument for Assessing the Quality of Life of People with Diabetes. Diabetes-39. *Medical Care*, 35: 440-453.

Bradley, C. & Speight, J. (2002) Patient Perceptions of Diabetes and Diabetes Therapy: Assessing Quality of Life. *Diabetes Metabolism, Research, Reviews*, 18: S64-S69.

Bradley, C. (1993) Designing Medical and Educational Intervention Studies: A Review of Some Alternatives to Conventional Randomized Controlled Trials. *Diabetes Care*, 16: 509-518.

Bradley, C. (1996a) The Well-Being Questionnaire. In Bradley, C. (Ed) *Handbook of Psychology and Diabetes.* (2nd Ed): 111-132. Netherlands. Harwood.

Bradley, C. (1996b) Diabetes Treatment Satisfaction Questionnaire (DTSQ). In Bradley, C. (Ed) *Handbook of Psychology and Diabetes.* (2nd Ed): 89-109. Netherlands. Harwood.

Bradley, C. (1997) Psychological Issues in Clinical Trial Design. *Irish Journal of Psychology*, 18: 67-87.

Bradley, C., Todd, C., Gorton, T., Symonds, E., Martin, A., Plowright, R. (1999). The Development of an Individualized Questionnaire Measure of Perceived Impact of Diabetes on Quality of Life: The ADDQoL. *Quality of Life Research.* 8: 79-91.

Brand-Miller, J., Hayne, S., Petocz, P., Colgiuri, S. (2003). Low-Glycemic Index Diets in the Management of Diabetes. A Meta-Analysis of Randomized Controlled Trials. *Diabetes Care.* 26, 8: 2261-2267.

Brazier, J.E., Harper, R., Jones, N.M.B., O'Cathian, Thomas, K.J., Usherwood, T. & Westlake, L. (1992) Validating the SF36. *British Medical Journal*: 305, 646.

British Medical Association and Royal Pharmaceutical Society of Great Britain (2004) British National Formulary. Pharmaceutical Press, Oxon.

Brown, G.C., Brown, M.M., Sharma, S., Brown, H., Gozum, M., Denton, P. (2000). Quality of Life Associated with Diabetes Mellitus in an Adult Population. *Journal of Diabetes and Its Complications.* 14: 18-24.

Brown, S. (1988) Effects of Educational Interventions in Diabetes Care: A Meta-Analysis of Findings. *Nursing Research*, 37: 223-230.

Brown, S. (1992) Meta-Analysis of Diabetes Patient Education Research: Variations in Intervention Effects Across Studies. *Research in Nursing and Health*, 15: 409-419.

Brown, S. (1999) Interventions to Promote Diabetes Self-Management: State of the Science. *The Diabetes Educator*, Suppl, 52-61.

Brown, S. A., Garcia, A. A., Kouzekanani, K., and Hanis, C. L. (2002) Culturally Competent Diabetes Self-Management Education for Mexican Americans: The Starr County Border Health Initiative, *Diabetes Care*, 25: 259-268.

Brown, S. & Hanis, C. L. (1999) Culturally Competent Diabetes Education for Mexican Americans: The Starr County Study. *Diabetes Educator*, 25: 226-236.

Brown, S.A., Upchurch, S., Anding, R., Winter, M & Ramirez, G. (1996) Promoting Weight Loss in Type II Diabetes. *Diabetes Care,* 19: 613-624.

Brownell, K.D. (1998). Diet, Exercise and Behavioural Intervention: The Nonpharmacological Approach. *European Journal of Clinical Investigation,* 28, S2: 19-22.

Cabrera-Pivaral, C. E., Gonzalez-Perez, G., Vega-Lopez, G., Gonzalez-Hita, M., Centeno-Lopez, M., Gonzalez-Ortiz, M., Martinez-Abundis, E., and Ojeda, A. G. (2000). Effects of Behavior-Modifying Education in the Metabolic Profile of the Type 2 Diabetes Mellitus Patient. *Journal of Diabetes and its Complications*, 14: 322-326.

Calle-Pascual, A. L., Rodriguez, C., Camacho, F., Sanchez, R., Martin-Alvarez, P. J., Yuste, E., Hidalgo, I., Diaz, R. J., Calle, J. R., Charro, A. L. (1992) Behaviour Modification in Obese Subjects with Type 2 Diabetes Mellitus. *Diabetes Research and ClinicalPractice.*15:157-162.

Campbell, E. M., Redman, S., Moffitt, P. S., Sanson-Fisher, R. W. (1996) The Relative Effectiveness of Educational and Behavioural Instruction Programs for Patients with NIDDM: A Randomized Trial. *The Diabetes Educator.* 22, 4: 379-386.

Campbell, L. V., Barth, R., Gosper, J. K., Jupp, J. J., Simons, L. A., and Chisholm, D. J (1990). Impact of Intensive Educational Approach to Dietary Change in NIDDM. *Diabetes Care*, 13: 841-847.

Chan, J., Rimm, E., Colditz, G., Stampfer, M & Willett W. (1994) Obesity, Fat Distribution, and Weight Gain as Risk Factors for Clinical Diabetes in Men. *Diabetes Care,* 17: 1-10.

Christensen, L. (2001) The Effect of Food Intake on Mood. *Clinical Nutrition*, 20, S1: 161-166.

Ciechanowski, P.S., Katon, W.J., Russo, J.E. (2000). Depression and Diabetes. Impact of Depressive Symptoms on Adherence, Function, and Costs. *Arch Intern Med.* 160: 3278-3285.

Claiborne, N., Massara, E. (2000). Mental Quality of Life: An Indicator of Unmet Needs in Patients with Diabetes. *Social Work in Health Care*. 32, 1: 25-43.

Clark Jr, C.M. (1998). Oral Therapy in Type 2 Diabetes: Pharmacological Properties and Clinical Use of Currently Available Agents. *Diabetes Spectrum*. 11, 4: 211-221.

Clark, D.O. (1997). Physical Activity Efficacy and Effectiveness Among Older Adults and Minorities. *Diabetes Care*. 20, 7: 1176-1182.

Clark, M. & Hampson, S.E. (2001) Implementing a Psychological Intervention to Improve Lifestyle Self-Management in Type 2 Diabetes. *Patient Education and Counseling*, 42: 247-256.

Clark, M., Hampson, S.E., Avery, L., Simpson, R. (2004) Effects of a Tailored Lifestyle Self-Management Intervention in Patients with Type 2 Diabetes. *British Journal of Health Psychology*. 9: 365-379.

Clarke, P., Gray, A., Legood R., Briggs A. & Holman R. (2003) The Impact of Diabetes-Related Complications on Healthcare Costs: Results from the United Kingdom Prospective Diabetes Study (UKPDS Study No. 65). *Diabetic Medicine*, 20: 442-450.

Clement, S. (1995) Diabetes Self-Management Education. *Diabetes Care*, 18, 1204-1214.

Coates, V.E., Boore, J.R.P. (1996) Knowledge and Diabetes Self-Management. *Patient Education and Counselling*, 29: 99-108.

Cohen, S., & Wills, T.A. (1985) Stress, Social Support, and the Buffering Hypothesis. *Psychological Bulletin*, 98: 310-357.

Connell, C.M., Davis, W.K., Gallant, M.P., Sharpe, P.A. (1994). Impact of Social Support, Social Cognitive Variables and Perceived Threat on Depression Among Adults with Diabetes. *Health Psychology*. 13, 3: 263-273.

Connell, C.M., Fisher, E.B., Houston, C.A. (1992). Relationships Among Social Support, Diabetes Outcomes, and Morale for Older Men and Women. *Journal of Aging and Health*. 4, 1: 77-100.

Cook, T.D. & Campbell, D.T. (1979) *Quasi-Experimentation: Design and Analysis Issues for Field Settings*. Chicago, Rand McNally.

Corabian, P., Harstall, C. (2001) Patient Diabetes Education in the Management of Adult Type 2 Diabetes. *Health Technology Assessment*, 23. Alberta Heritage Foundation for Medical Research.

Coster, S., Gulliford, M.C., Seed, P.T., Powrie, J.K., Swaminathan, R. (2000). Self-Monitoring in Type 2 Diabetes Mellitus: A Meta-Analysis. *Diabetic Medicine*. 17: 755-761.

Cramer, J.A., (2004). A Systematic Review of Adherence with Medications for Diabetes. *Diabetes Care*. 27, 5: 1218-1224.

Currie C.J., Kraus, D., Morgan, C.L., Gill, L., Stott, N.C.H., Peters J.R. (1997) NHS Acute Sector Expenditure for Diabetes: The Present, Future, and Excess In-Patient Cost of Care. *Diabetic Medicine*, 14: 686-692.

Day, J.L., Bodmer, C.W., Dunn, O.M. (1996). Development of a Questionnaire Identifying Factors Responsible for Successful Self-Management of Insulin-Treated Diabetes. *Diabetic Medicine*. 13; 564-573.

DCCT Research Group (1988) The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications Insulin-Dependent Diabetes Mellitus. *New England Journal of Medicine*. 329: 977-986.

DCCT Research Group: (1988) Reliability and Validity of a Diabetes Quality of Life Measure for the Diabetes Control and Complications Trial (DCCT). *Diabetes Care*, 11: 725-732.

De Groot, M., Anderson, R., Freedland, K.E., Clouse, R.E. Lustman, P.J. (2001). Association of Depression and Diabetes Complications: A Meta-Analysis. *Psychosomatic Medicine.* 63: 619-630.

De Ridder, D., Schreurs, K. (1996) Coping, Social Support and Chronic Disease: A Research Agenda. *Psychology, Health and Medicine.* 1: 71-82.

De Visser, C.L., Bilo, H.J.G., Groenier, K.H., De Visser, W., Meyboom-de Jong, B. (2002). The Influence of Cardiovascular Disease on Quality of Life in Type 2 Diabetics. *Quality of Life Research.* 11: 249-261.

De Vries, H., Mudde, A., Dijtesta, A. (2000) The Attitude-Social Influence Efficacy Model Applied to the Prediction of Motivational Transitions in the Process of Smoking Cessation. In Abraham, C. & Norman, P. (Eds) Understanding & Changing Health Behaviour: From Health Beliefs to Self-Regulation: 165-187. Amsterdam, Netherlands, Harwood.

DECODE Study Group (1998) Will New Diagnostic Criteria for Diabetes Mellitus Change Phenotype of Patients with Diabetes? Reanalysis of the European Epidemiological Data. *British Medical Journal*, 317: 371-375.

Department of Health (2001) National Service Framework for Diabetes. DOH, London.

D'Eramo-Melkus, G. A., Wylie-Rosett, J., Hagan, J. A. (1992). Metabolic Impact of Education in NIDDM. *Diabetes Care.* 15,7: 864-869.

Di Loretto, C., Fanelli, C., Lucidi, P., Murdolo, G., De Cicco, A., Parlanti, N., Santeusanio, F., Brunetti, P., De Feo, P. (2003) Validation of a Counseling Strategy to Promote the Adoption and the Maintenance of Physical Activity by Type 2 Diabetic Subjects. *Diabetes Care*, 26: 404-408.

Diabetes UK (2000) Diabetes in the UK – The Missing Million: Perceptions and Reality of Diabetes Today. London.

Domenech, M. I., Assad, D., Mazzei, M. E., Kronsbein, P., Gagliardino, J. J. (1995) Evaluation of the Effectiveness of an Ambulatory Teaching/Treatment Programme for Non-Insulin Dependent Type 2 Diabetic Patients. *Acta Diabetologia*. 32: 143-147.

Duncan, G.E., Perri, M.G., Theriaque, D.W., Hutson, A.D., Eckel, R.H., Stacpoole, P.W. (2003). Exercise Training, Without Weight Loss, Increases Insulin Sensitivity and Postheparin Plasma Lipase Activity in Previously Sedentary Adults. *Diabetes Care*. 26, 3: 557-562.

Dunn, S.M., Bryson, J.M., Hoskins, P.L., Alford, J.B., Handelsman, D.J. & Turtle, J.R. (1984) Development of the Diabetes Knowledge (DKN) Scales: Forms DKNA, DKNB and DKNC. *Diabetes Care*, 7: 36-41.

Eachus, J., Williams, M., Chan, P., Smith, G.D., Grainge, M., et al. (1996) Deprivation and Cause-Specific Morbidity: Evidence from the Somerset and Avon Survey of Health. *British Medical Journal*, 312: 287-292.

Egede, L.E. (2004). Diabetes, Major Depression and Functional Disability Among U.S. Adults. *Diabetes Care*. 27: 421-428.

Egede, L.E., Zheng, D. (2003). Independent Factors Associated with Major Depressive Disorder in a National Sample of Individuals with Diabetes. *Diabetes Care*. 26, 1: 104-111.

Egede, L.E., Zheng, D., Simpson, K. (2002). Comorbid Depression is Associated with Increased Health Care Use and Expenditures in Individuals with Diabetes. *Diabetes Care*. 25, 3: 464-470.

Eiser, J.R., Riazi, A., Eiser, C., Hammersley, S., Tooke, J.E. (2001). Predictors of Psychological Well-Being in Types 1 and 2 Diabetes. *Psychology and Health*. 16: 99-110.

Ellis, S.E., Speroff, T., Dittus, R.S., Brown, A., Pichert, J.A. & Elasy, T.A. (2004). Diabetes Patient Education: A Meta-Analysis and Meta-Regression. *Patient Education and Counselling*, 52: 97-105.

Evans, J.M.M, Newton, R.W., Ruta, D.A., MacDonald, T.M & Morris, A.D. (2000) Socio-Economic Status, Obesity and Prevalence of Type 1 and Type 2 Diabetes Mellitus. *Diabetic Medicine*, 478-480.

Evans, J.M.M., Newton, R.W., Ruta, D.A., MacDonald, T.M., Stevenson, R.J., Morris, A.D. (1999). Frequency of Blood Glucose Monitoring in Relation to Glycaemic Control: Observational Study with Diabetes Database. *British Medical Journal.* 319: 83-86.

Evers, A.W. Kraaimaat, F.W., van Riel, P.L., de Jong. (2002) Tailored Cognitive Behavioral Therapy in Early Rheumatoid Arthritis for Patients at Risk: A Randomized Controlled Trial. *Pain*, 100: 141-153.

Ewart, C.K. (1991). Social Action Theory for a Public Health Psychology. *American Psychologist*, 46: 931-946.

Faas, A., Schellevis, F.G., Van Eijk, J.T.M., (1997). The Efficacy of Self-Monitoring of Blood Glucose in NIDDM Subjects. A Criteria-Based Literature Review. *Diabetes Care.* 20, 9: 1482-1486.

Fain, J.A., Nettles, A., Funnel, M.M & Charon Prochownik, D (1999) Diabetes Patient Education Research: An Integrative Literature Review. *The Diabetes Educator*, 25: 7-15.

Falkenberg, M. G. K., Elwing, B. E., Goransson, A. M., Hellstrand, B. E. S., and Riis, U. M. (1986) Problem Oriented Participatory Education in the Guidance of Adults with Non-Insulin-Treated Type II Diabetes Mellitus. *Scandinavian Journal of Primary Health Care.* 3:157-164.

Feine, J.S., Awad, M.A. & Lung, J.P. (1998) The Impact of Patient Preference on the Design and Interpretation of Clinical Trials. *Community Dental Oral Epidemiology*, 26: 70-74.

Feste, C., Anderson, R.M. (1995) Empowerment: From Philosophy to Practice. *Patient Education and Counseling*, 26: 139-144.

Fischbacher, C.M., Bhopal, R., Rutter, M.K., Unwin, N.C., Marshall, S.M., White, M. & Alberti, K.G.M.M (2003) Microalbuminuria is More Frequent in South Asian than in European Origin Populations: A Comparative Study in Newcastle, UK. *Diabetic Medicine,* 20, 31-36.

Fitzgerald, J.T., Davis, W.K., Connell, C.M., Hess, G.E., Funnell, M.M., Hiss R.G. (1996) Development and Validation of the Diabetes Care Profile. *Evaluation of Health Professions,* 19: 208-230.

Fitzgerald, J.T., Funnell, M.M., Hess, G.E., Barr, P.A., Anderson, R.M., Hiss, R.G., Davis, W.K. (1998). The Reliability and Validity of a Brief Diabetes Knowledge Test. *Diabetes Care*. 21, 5: 706-710.

Fitzpatrick, R., Davey, C., Buxton, M.J., Jones, D.R. (1998) Evaluating Patient Based Outcome Measures for Use in Clinical Trials. *Health Technology Assessment*, 2: 1-74.

Ford, E., Malarcher, A., Herman, W. & Aubert, R. (1994) Diabetes Mellitus and Cigarette Smoking Findings from the 1989 National Health Interview Survey. *Diabetes Care*, 17: 688-692.

Ford, E.S. & Herman, W.H. (1995). Leisure-Time Activity Patterns in the U.S. Diabetic Population. *Diabetes Care*, 18: 27-33.

Franciosi, M., Pellegrini, F., De Berardis, G., Belfiglio, M., Cavaliere, D., Di Nardo, Barbara., Greenfield, S., Kaplan, S.H., Sacco, M., Tognoni, G., Valentini, M., Nicolucci, A., For the QuED Study Group. (2001). The Impact of Blood Glucose

Self-Monitoring on Metabolic Control and Quality of Life in Type 2 Diabetic Patients. An Urgent Need for Better Educational Strategies. *Diabetes Care.* 24, 11: 1870-1877.

Franke, R.H. & Kaul, J.D. (1978) The Hawthorne Experiments: First Statistical Interpretation. *American Sociological Review*, 43: 623-643.

Franz, M.J., Bantle, J.P., Beebe, C.A., Brunzell, J.D., Chiasson, J.L., Garg, A., Holzmeister, L.A., Hoogwerf, B., Mayer-Davis, E., Mooradian A.D., Purnell, J.Q., Wheeler, M. (2002). Evidence-Based Nutrition Principles and Recommendations for the Treatment and Prevention of Diabetes and Related Complications. *Diabetes Care.* 25, 1:148-198.

Fritsche, A., Stumvoll, M., Goebbel, S., Reinauer, K. M., Schmulling, R. M., and Haring, H. U. (1999). Long term Effect of a Structured Inpatient Diabetes Teaching and Treatment Programme in Type 2 Diabetic Patients: Influence of Mode of Follow-up. 46, 135-141.

Fukunishi, I., Horikawa, N., Yamazaki, T., Shirasaka, K., Kanno, K., Akimoto, M. (1998). Perception and Utilization of Social Support in Diabetic Control. *Diabetes Research and Clinical Practice.* 41: 207-211.

Fung, E.K., Lore, J. M. (2002) Randomized Controlled Trials for Evaluating Surgical Questions. *Archives of Otolaryngology.* 128: 631-634.

Gaede,P., Vedel,P., Parving,HH. & Pedersen,O. (1999) Intensified Multifactorial Intervention in Patients with Type 2 Diabetes Mellitus and Microalbuminuria: The Steno Type 2 Randomised Study. *Lancet*, 353: 617-622.

Gallant, M.P. (2003) The Influence of Social Support on Chronic Illness Self-Management: A Review and Directions for Research. *Health Education and Behavior,* 30: 170-195.

Gallichan, M. (1997). Self Monitoring of Glucose by People with Diabetes: Evidence Based Practice. *British Medical Journal.* 314: 964.

Garay-Sevilla, M.E., Malacara, J.M., Gutierrez-Roa, A., Gonzalez, E. (1999). Denial of Disease in Type 2 Diabetes Mellitus: Its Influence on Metabolic Control and Associated Factors. *Diabetic Medicine.* 16: 238-244.

Garcia, R., Suarez, R. (1996) Diabetes Education in the Elderly: A 5 year Follow-Up of an Interactive Approach. *Patient Education and Counseling.* 29: 87-97.

Garrard, J. Ostom Joynes, J. & Mullen L. (1987) Psychometric Study of Patient Knowledge Test. *Diabetes Care*, 10: 500-509.

Garratt, A.M., Schmidt, L., Fitzpatrick, R. (2002). Patient-assessed Health Outcome Measures for Diabetes: A Structured Review. *Diabetic Medicine.* 19: 1-11.

Gilden, J. L., Hendryx, M. S., Clar, S., Casia, C., Singh, S. P. (1992) Diabetes Support Groups Improve Health Care of Older Diabetic Patients. *Journal of American Geriatrics Society.* 40, 2: 147-150.

Glasgow, R.E. (1991). Compliance to Diabetes Regimens. Conceptualization, Complexity, and Determinants. *Patient Compliance in Medical Practice and Clinical Trials.* 17; 209-224.

Glasgow, R.E. (2003) Translating Research to Practice: Lessons Learned, Areas for Improvement, and Future Directions. *Diabetes Care*, 26: 2451-2456.

Glasgow, R.E. & Anderson, R.M. (1999) In Diabetes Care, Moving From Compliance to Adherence is Not Enough. *Diabetes Care*, 22: 2090-2091.

Glasgow, R.E. & Toobert, D.J. (1988). Social Environment and Regimen Adherence Among Type II Diabetic Patients. *Diabetes Care.* 11, 5: 377-386.

Glasgow, R. E. & Toobert, D. J. (2000) Brief, Computer-assisted Diabetes Dietary Self-management Counseling: Effects on Behavior, Physiologic Outcomes, and Quality of Life. *Med Care.* 38, 11: 1062-1073.

Glasgow, R.E., Barrera, M., McKay, H.G. & Boles (1999) Social Support, Self-Management, and Quality of Life Among Participants in an Internet-Based Diabetes Support Program: A Multi-Dimensional Investigation. *CyberPsychology & Behavior*, 2: 271-281.

Glasgow, R. E., Boles, S. M., McKay, H. G., Feil, E. G., Barrera Jr, M. (2003) The D-Net Diabetes Self-Management Program: Long-Term Implementation, Outcomes, and Generalization Results. *Preventive Medicine,* 36: 410-419.

Glasgow, R. E., Chance, P. A. La, Toobert, D. J., Brown, J., Hampson, S. E., Riddle, M. C. (1997c) Long Term Effects and Costs of Brief Behavioural Dietary Intervention for Patients with Diabetes Delivered from the Medical Office. *Patient Education and Counseling.* 32:175-184.

Glasgow, R.E., Eakin, E.G., Toobert, D.J. (1996). How Generalizable are the Results of Diabetes Self-Management Research? The Impact of Participation and Attrition. *The Diabetes Educator.* 22, 6: 573-585.

Glasgow, R.E., Hampson, S.E., Strycker, L.A., Ruggiero, L. (1997b). Personal-Model Beliefs and Social-Environmental Barriers Related to Diabetes Self-Management. *Diabetes Care.* 20, 4; 556-561.

Glasgow, R.E, Hiss, R.G., Anderson, R.M., Friedman, N.M., Hayward, R.A., Marrero., D.G., Taylor., C.B., Vinicor, F. (2001) Report of the Health Care Delivery Work Group: Behavioral Research Related to the Establishment of a Chronic Disease Model for Diabetes Care. *Diabetes Care*, 24: 124-130

Glasgow, R.E., McKay, H.G., Piette, J.D., Reynolds, K.D. (2001). The RE-AIM Framework for Evaluating Interventions: What Can it Tell Us About Approaches to Chronic Illness Management? *Patient Education and Counseling*. 44: 119-127.

Glasgow, R.E., Osteen, V.L. (1992). Evaluating Diabetes Education. Are We Measuring the Most Important Outcomes? *Diabetes Care.* 15, 10: 1423-1432.

Glasgow, R.E., Ruggiero, L., Eakin, E.G., Dryfoos, J., Chobanian, L. (1997a). Quality of Life and Associated Characteristics in a Large National Sample of Adults with Diabetes. *Diabetes Care.* 20, 4: 562-567.

Glasgow, R.E., Toobert, D.J., Hampson, S.E. & Stryker, L.A. (2002) Implementation, Generalization and Long Term Results of the "Choosing Well" Diabetes Self-Management Intervention. *Patient Education and Counseling.* 1598: 1-8.

Glasgow, R.E., Toobert, D.J., Hampson, S.E. (1996) Effects of a Brief Office-Based Intervention to Facilitate Diabetes Dietary Self-Management. *Diabetes Care*, 19: 835-842.

Glasgow, R.E., Toobert, D.J., Riddle, M., Donnelly, J., Mitchell, D.L., Calder, D. (1989). Diabetes-Specific Social Learning Variables and Self-Care Behaviors Among Persons with Type II Diabetes. *Health Psychology.* 8, 3; 285-303.

Glasgow, R.E., Toobert, K.J., Hampson, S.E., Wilson, W. (1995). Behavioral Research on Diabetes at the Oregon Research Institute. *Annals of Behavioral Medicine.* 17: 32-40.

Glasgow, R. E., Toobert, D. J., Hampson, S. E. (1996). Effects of a Brief Office-Based Intervention to Facilitate Diabetes Dietary Self-Management. *Diabetes Care.* 19, 8: 835-842.

Glasgow, R. E., Toobert, D. J., Hampson, S. E., and Noell, J. W. (1995) A Brief Office-Based Intervention to Facilitate Diabetes Dietary Self-Management. *Health Education Research.* 10, 4: 467-478.

Glasgow, R. E., Toobert, D. J., Hampson, S. E., Brown, J. E., Lewinsohn, P. M., Donnelly, J. (1992) Improving Self-Care Among Older Patients With Type II

Diabetes: The "Sixty Something..." Study. *Patient Education and Counseling.* 19: 61-74.

Glasgow, R.E, Wagner, E.H., Kaplan, R.M., Vinicor, F., Smith, L. & Norman, J. (1999) If Diabetes is a Public Health Problem, Why Not Treat is as One? A Population-Based Approach to Chronic Illness. *Annals of Behavioral Medicine*, 21: 159-170.

Goddijn, P.P.M., Bilo, H.J.G., Feskens, E.J.M., Groenier, K.H., Van der Zees, Meyboom-de Jong, B. (1999). Longitudinal Study on Glycaemic Control and Quality of Life in Patients with Type 2 Diabetes Mellitus Referred for Intensified Control. *Diabetic Medicine.* 16; 23-30.

Goldhaber-Fiebert, J. D., Goldhaber-Fiebert, S. N., Tristan, M. L., Nathan, D. M. (2003) Randomized Controlled Community-Based Nutrition and Exercise Intervention improves Glycemia and Cardiovascular Risk Factors in Type 2 Diabetic Patients in Rural Costa Rica. *Diabetes Care*, 26, 1: 24-29.

Goldney, R.D., Phillips, P.J., Fisher, L.J., Wilson, D.H. (2004). Diabetes, Depression, and Quality of Life. A Population Study. *Diabetes Care.* 27, 5: 1066-1070.

Gollwitzer, P.M., Oettingen, G. (2000) The Emergence and Implementation of Health Goals. In Abraham, C. & Norman, P. (Eds) Understanding & Changing Health Behaviour: From Health Beliefs to Self-Regulation: 229-260. Amsterdam, Netherlands, Harwood.

Gollwitzer, P.M. (1990) Action Phases and Mind-Sets. In Higgins, E.T. & Sorrentino, R.M. (Eds) *Handbook of Motivation and Cognition: Foundations of Social Behavior*, 2: 53-92. New York: Guildford.

Gollwitzer, P.M. (1993) Goal Achievement: The Role of Intentions. In Stroebe, W & Hewstone, M. (Eds) *European Review of Social Psychology*, 4. Chichester: Wiley.

Goodall, T.A. & Halford, W.K. (1991) Self-Management of Diabetes Mellitus: A Critical Review. *Health Psychology*, 1-8.

Goodwin, J.S., Hunt, W.C., Key, C.R. & Sarnet, J.M. (1987) The Effect of Marital Status on Stage, Treatment, and Survival of Cancer Patients. *JAMA*, 258: 3125-3130.

Gregg, E.W., Gerzoff, R.B, Thompson, T.J. & Williamson, D.F. (2004). Trying to Lose Weight, Losing Weight, and 9-Year Mortality in Overweight U.S. Adults with Diabetes. *Diabetes Care*, 27: 657-662.

Griffin,S., Kinmouth,A.L., Skinner,C. & Kelly, J. (1998) *Educational and Psychosocial Intervention for Adults with Diabetes.* British Diabetic Association. London.

Grigsby, A.B., Anderson, R.J., Freedland, K.E., Clouse, R.E., Lustman, P.J. (2002). Prevalence of Anxiety in Adults with Diabetes. A Systematic Review. *Journal of Psychosomatic Research*. 53:1053-1060.

Gruesser, M., Bott, U., Ellermann, P., Kronsbein, P., Joergens, V. (1993) Evaluation of a Structured Treatment and Teaching Program for Non-Insulin-Treated Type II Diabetic Outpatients in Germany After the Nationwide Introduction of Reimbursement Policy for Physicians. *Diabetes Care*. 16:1268-1275.

Gruesser, M., Hartmann, P., Schlottmann, N., Joergens, V. (1996) Structured Treatment and Teaching Programme for Type 2 Diabetic Patients on Conventional Insulin Treatment: Evaluation of Reimbursement Policy. *Patient Education and Counseling*. 29: 123-130.

Guare, J. C., Wing, R. R., Grant, A. (1995) Comparison of Obese NIDDM and Nondiabetic Women: Short- and Long-Term Weight Loss. *Obesity Research*. 3, 4: 329-335.

Gunton, J.E., Davies, L., Wilmshurst E., Fulcher, G., McElduff, A. (2002) Cigarette Smoking Affects Glycemic Control in Diabetes. *Diabetes Care*, 24: 796-797.

Haire-Joshu, D, Glasgow, R.E.& Tibbs, T.L. (1999) Smoking and Diabetes. *Diabetes Care*, 22: 1887-1898.

Hampson, S.E., Glasgow, R.E. & Toobert, D.J. (1990). Personal Models of Diabetes and Their Relation to Self-Care Activities. *Health Psychology*, 9: 632-646.

Hampson, S.E., Glasgow, R.E., Foster, L.S. (1995). Personal Models of Diabetes Among Older Adults: Relationship to Self-Management and Other Variables. *The Diabetes Educator.* 21, 4; 300-307.

Hampson, S.E., Glasgow, R.E., Strycker, L.A. (2000). Beliefs Versus Feelings: A Comparison of Personal Models and Depression for Predicting Multiple Outcomes in Diabetes. *British Journal of Health Psychology.* 5: 27-40.

Hanninen, J., Takala, J., Keinanen-Kiukaanniemi, S. (1998). Quality of Life in NIDDM Patients Assessed with the SF-20 Questionnaire. *Diabetes Research and Clinical Practice.* 42: 17-27.

Hanninen, J., Takala, J., Keinanen-Kiukaanniemi, S. (2001). Good Continuity of Care May Improve Quality of Life in Type 2 Diabetes. *Diabetes Research and Clinical Practice.* 51: 21-27.

Hanninen, J.A., Takala, J.K., Keinanen-Kiukaanniemi, S.M. (1999). Depression in Subjects with Type 2 Diabetes. *Diabetes Care.* **22**, 6: 997.

Harris, M.I., Cowie, C.C., Stern, M.P., Boyko, E.J., Reiber, G.E. & Bennett, P.H. (1995) *Diabetes in America*, 2nd Ed. National Institute of Health Publication No 95-1468.

Hartwell, S. L., Kaplan, R. M., and Wallace, J. P. (1986) Comparison of Behavioral Interventions for Control of Type II Diabetes Mellitus. *Behavior Therapy.* 17: 447-461.

Haynes, R.B., Taylor, D.W., Sackett, D.L. (Eds) (1979) *Compliance in Health Care.* Baltimore, Maryland, John Hopkins Press.

Hays, L.M. & Clark, D.O. (1999). Correlates of Physical Activity in a Sample of Older Adults with Type 2 Diabetes. *Diabetes Care*. 22, 5: 706.

Heckhausen, H. (1991) *Motivation and Action.* Berlin: Springer-Verlag.

Heisler M., Smith, D.M., Hayward, R.A., Krein, S.L. & Kerr, E.A. (2003) How Well Do Patients' Assessments of Their Diabetes Self-Management Correlate with Actual Glycemic Control and Receipt of Recommended Diabetes Services? *Diabetes Care*, 26: 738-743.

Heitzmann, C. A., Kaplan, R. M., Wilson, D. K., Sandler, J. (1987) Sex Differences in Weight Loss Among Adults with Type II Diabetes Mellitus. *Journal of Behavioral Medicine*. 10, 2: 197-211.

Henry, J. L., Wilson, P. H., Bruce, D. G., Chisholm, D. J., Rawling, P. J. (1997) Cognitive-Behavioural Stress Management for Patients with Non-Insulin Dependent Diabetes Mellitus. *Psychology, Health and Medicine.* 2: 109-118.

Hermann, C. (1997) International Experiences with the Hospital Anxiety and Depression Scale – A Review of Validation Data and Clinical Results. *Journal of Psychosomatic Research*. 47, 1: 17-41.

Hewett, J.E., Anderson, S.K. & Minor, M.A. (1992) Statistical Analyses for Research in Arthritis When Assessing Change. *Arthritis Care and Research*, 5:74-80.

Hirsch, A., Bartholomae, Volmer, T. (2000). Dimensions of Quality of Life in People with Non-Insulin-Dependent Diabetes. *Quality of Life Research.* 9: 207-218.

Howard, A.A., Arnsten, J.A & Gourevitch, M.N. (2004). Effect of Alcohol Consumption on Diabetes Mellitus: A Systematic Review. *Annals of Internal Medicine*, 140: 211-219.

Hunt, S.M, McEwen, J., McKenna, SP. (1985) Measuring Health Status: A New Tool for Clinicians and Epidemiologists. *Journal of Royal College of General Practitioners,* 35: 185-188.

Inzucchi, S.E. (2002). Oral Antihyperglycemic Therapy for Type 2 Diabetes. *JAMA.* 287, 3: 360-372.

Jablon, S. L., Naliboff, B. D., Gilmore, S. L., Rosenthal, M. J. (1997) Effects of Relaxation Training on Glucose Tolerance and Diabetic Control in Type II Diabetes. *Appl Psychophysiol Biofeedback.* 22, 3: 155-169.

Jacobson, A.M., De Groot, M., Samson, J.A. (1994) The Evaluation of Two Measures of Quality of Life in Patients with Type I and Type II Diabetes. *Diabetes Care,* 17: 267-274.

Janz, N.K. & Becker, M.H. (1984). The Health Belief Model: A Decade Later. *Health Education Quarterly,* 11, 91-105.

Jenkins, C (2003) Self-Management in Diabetes: The Dynamics of Behaviour Change. *Journal of Diabetes Nursing,*.7: 225-227.

Jenkinson, C., Layte, R. & Lawrence, K. (1997) Development and Testing of the Medical Outcomes Study 36-Item Short Form Health Survey Summary Scale Scores in the United Kingdom: Results from a Large-Scare Survey and a Clinical Trial. *Medical Care*, 4: 410-416.

Jenkinson, C., Layte, R., Wright, L., & Coulter, A. (1996) *The UK SF-36: An Analysis and Interpretation Manual.* HSRU: Oxford University.

Jones, H. Edwards, L., Vallis, T.M., Ruggiero, L. Rossi, S.R., Rossi, .S., Greene, G. Prochaska, J.O. & Zinman, B. (2003) Changes in Diabetes Self-Care Behaviors Make a Difference in Glycemic Control: The Diabetes Stages of Change (DiSC) Study. *Diabetes Care*, 26: 732-737.

Kaplan, R. M., Atkins, C. J., Wilson, D. K. (1988) The Cost-Utility of Diet and Exercise Interventions in Non-Insulin-Dependent Diabetes Mellitus. *Health Promotion.* 2: 331-340.

Karter, A.J., Ackerson, L.M., Darbinian, J.A., D'Agostino Jr, R.B., Ferrara, A., Liu, J., Selby, J.V. (2001) Self-Monitoring of Blood Glucose Levels and Glycemic Control: The Northern California Kaiser Permanente Diabetes Registry. *The American Journal of Medicine.* III: 1-9.

Karter, A.J., Ferrara, A., Darbinian, J.A., Ackerson, L.M., Selby, J.V. (2000). Self-Monitoring of Blood Glucose. Language and Financial Barriers in a Managed Care Population with Diabetes. *Diabetes Care.* 23, 4: 477-483.

Katon, W., VonKorff, M., Ciechanowski P., Russo, J., Lin, E., Simon, G., Ludman, E., Walker, E., Bush, T., Young, B. (2004). Behavioral and Clinical Factors Associated with Depression Among Individuals with Diabetes. *Diabetes Care.* 27, 4: 914-910.

Kavanagh, D.J., Gooley, S. Wilson, P.H. (1993). Prediction of Adherence and Control in Diabetes. *Journal of Behavioral Medicine.* 16, 5; 509-522.

Keefe, F.J., Caldwell, D.S. Baucom, D., Salley, A., Robinson, E. Timmons, K. et al. (1999) Spouse Assisted Coping Skills Training in the Management of Knee Pain in Osteoarthritis: Long Term Follow-Up Results. *Arthritis, Care & Research*, 12: 101-111.

Keeling, D.I., Price, P.E., Jones, E., Harding, K.G. (1996). Social Support: Some Pragmatic Implications for Health Care Professionals. *Journal of Advanced Nursing.* 23: 76-81.

Keers, J. C., Blaauwwiekel, E. E., Hania, M., Bouma, J., Scholten-Jaegers, S. M. H. J., Sanderman, R., Links, T. P. (2004) Diabetes Rehabilitation: Development and First Results of a Multidisciplinary Intensive Education Program for Patients with Prolonged Self-Management Difficulties. *Patient Education and Counseling*, 52: 151-157.

Kenardy, J., Mensch, M., Bowen, K., Green, B., Walton, J. (2002) Group Therapy for Binge Eating in Type 2 Diabetes: A Randomized Trial. *Diabetic Medicine*, 19: 234-239.

Kessing, L.V., Nilsson, F. M., Siersma, V., Anderson, P.K. (2003). No Increased Risk of Developing Depression in Diabetes Compared to Other Chronic Illness. *Diabetes Research and Clinical Practice.* 62: 113-121.

Keyserling, T. C., Samuel-Hodge, C. D., Ammerman, A. S., Ainsworth, B. E., Henriquez-Roldan, C. F., Elasy, T. A., Skelly, A. H., Johnston, L. F., Bangdiwala, S. I. A (2002) Randomized Trial of an Intervention to Improve Self-Care Behaviors of African-American Women with Type 2 Diabetes. *Diabetes Care,* 25:1576-1583.

Khan, K.S., ter Riet, G., Glanville, J., Sowden, D. & Kleijnen, J. (2001) Undertaking Systematic Reviews of Research on Effectivenesss: CRD's Guidance for Those Carrying Out or Commissioning Reviews. *CRD Report Number 4 (2nd Ed.) NHS Centre for Reviews and Dissemination*, University of York.

Kingery, P.M., Glasgow, R.E. (1989). Self-Efficacy and Outcome Expectations in the Self-Regulation of Non-Insulin Dependent Diabetes Mellitus. *Health Education.* 20, 7; 13-19.

Kirk, A. F., Higgins, L. A., Hughes, A. R., Fisher, B. M., Mutrie, N., Hillis, S., MacIntyre, P. D. (2001) A Randomized, Controlled Trial to Study the Effect of Exercise Consultation on the Promotion of Physical Activity in People with Type 2 Diabetes: A Pilot Study. *Diabetic Med.* 18: 877-882.

Kirk, A., Mutrie, N., MacIntyre, P., Fisher, M. (2003) Increasing Physical Activity in People with Type 2 Diabetes. *Diabetes Care,* 26: 1186-1192.

Klein, R. (1995) Hyperglycemia and Microvascular and Macrovascular Disease in Diabetes. *Diabetes Care,* 18: 258-268.

Klein, R., Klein, B.E.K., Moss, S.E., Davis, M.D., DeMets, D,L. (1984) The Wisconsin Epidemiologic Study of Diabetic Retinopathy. III. Prevalence and Risk of Diabetic Retinopathy when Age at Diagnosis is 30 or More Years. *Archives of Opthamology*, 102: 527-532.

Klein, S., Sheard, N.F., Pi-Sunyer, X., Daly, A., Wylie-Rosett, J., Kulkarni, K. & Clark, N.G. (2004) Weight Management Through Lifestyle Modification for the Prevention and Management of Type 2 Diabetes: Rationale and Strategies. *Diabetes Care*, 27: 2067-2073.

Knowler, W.C., Barrett-Conner, E., Fowler S.E., Hamman, R.F., Lachia, J.M, Walker, E.A., Nathan, D.M for the Diabetes Prevention Program Research Group (2002). Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin. *New England Journal of Medicine*. 346, 393-403.

Kohen D., Burgess, A.P., Catalan J., Lant A. (1998). The Role of Anxiety and Depression in Quality of Life and Symptom Reporting in People with Diabetes Mellitus. *Quality of Life Research*. 7: 197-204.

Kristal, A.R., Shattuck., A.L. & Henry, H.J. (1990) Patterns of Dietary Behavior Associated with Selecting Diets Low in Fat: Reliability and Validity of a Behavioral Approach to Dietary Assessment. *Journal of American Dietary Association,* 90: 214-220.

Kronsbein, P., Jorgens, V., Mulhauser, I., Scholz, V., Venhaus, A., Berger, M. (1988) Evaluation of a Structured Treatment and Teaching Programme on Non-Insulin-Dependent Diabetes. *The Lancet*: 1407-1410.

Laitinen, J., Uusitupa, M., Ahola, I., Laakso, M., Siitonen, O. (1994) Metabolic and Dietary Variables Associated with Glycaemic Control In Patients with Recently Diagnosed Type II Diabetes Mellitus. *Diabetes Nutrition and Metabolism*. 7,2: 77-87.

Lane, J. D., McCaskill, C. C., Ross, S. L., Feinglos, M. N., Surwit, R. S. (1993) Relaxation Training for NIDDM: Predicting Who May Benefit. *Diabetes Care.* 16:1087-1094.

Lazarus, R.S., Folkman, S. (1984) *Stress, Appraisal and Coping.* New York: Springer.

Leese B. (1992) The Costs of Diabetes and Its Complications. *Social Science and Medicine*, 35, 10: 1303-1310.

Leventhal, H., Benyamini, Y., Brownlee, S., Diefenbach, M., Leventhal, E. Patrick Miller, R. & Robitaille, C. (1997) Illness Representations: Theoretical Foundations. In Weinman, J.A. & Petrie, K.J. (Eds) *Perceptions of Health and Illness. Current Research and Applications.* Amsterdam, Netherlands. Harwood.

Leventhal, H., Nerenz, D.R., and Steele, D.F. (1984) Illness Representations and Coping with Health Threats. In Baum, A., & Singer, J. (Eds*). A Handbook of Psychology and Health.* Hillsdale, NJ: Erlbaum, 219-252.

Lewis, K.S., Jennings, A.M., Ward, J.D. & Bradley C. (1990) Health Belief Scales Developed Specifically for People with Tablet-Treated Type 2 Diabetes. *Diabetic Medicine*, 7: 148-155.

Lewis, R., Dixon, J. (2004). Rethinking Management of Chronic Diseases. *British Medical Journal.* 328: 220-222.

Llabre, M.M, Spitzer, S.B., Saab, P.G., Ironson, G.H & Schneiderman, N. (1991) The Reliability and Specificity of Delta Versus Residualized Change as Measures of Cardiovascular Reactivity to Behavioral Challenges. *Psychophysiology*, 28: 701-711.

Lloyd C.E., Dyer P.H., Barnett A.H. (2000). Prevalence of Symptoms of Depression and Anxiety in a Diabetes Clinic Population. *Diabetic Medicine.* 17:198-202.

Loveman, E., Cave, C., Green, C., Royle, P., Dunn, N., & Waugh, N. (2003) The Clinical and Cost-Effectiveness of Patient Education Models for Diabetes: A Systematic Review and Economic Evaluation. *Health Technology Assessments* , 7 (22).

Lustman, P. J., Feedland, K. E., Griffith, L. S., Clouse, R. E. (1998b) Predicting Response to Cognitive Behavior Therapy of Depression in Type 2 Diabetes. *General Hospital Psychiatry.* 20,5: 302-306.

Lustman, P. J., Griffith, L. S., Freedland, K. E., Kissel, S. S., Clouse, R. E. (1998a) Cognitive Behavior Therapy for Depression in Type 2 Diabetes Mellitus. *Annals of Internal Medicine*, 129: 613-621.

Lustman, P.J., Anderson, R.J., Freedland, K.E., De Groot, M., Carney, R.M., Clouse, R.E. (2000). Depression and Poor Glycemic Control. *Diabetes Care.* 23, 7: 934-942.

Mackinnon, A., Jorm, A.F., Christensen, H., Korten, A.E., Jacomb, P.A., Rodgers, B. (1999). A Short Form of the Positive and Negative Affect Schedule: Evaluation of Factorial Validity and Invariance Across Demographic Variables in a Community Sample. *Personality and Individual Differences.* 27: 405-416.

MacKinnon, D.P. (2001) Analysis of Mediating Variables in Prevention and Intervention Studies. In Cazares A., & Beatty L.A. (Eds) *Scientific Methods for Prevention Intervention Research.* (NIDA Research Monograph No. 139: 127-153). Washington, DC.

Maclean, D., Lo, R. (1998) The Non-Insulin Dependent Diabetic: Success and Failure in Compliance. *Australian Journal of Advanced Nursing.* 15, 4; 33-42.

Macrodimitris, S.D., Endler, N.S. (2001). Coping, Control, and Adjustment in Type 2 Diabetes. *Health Psychology.* 20, 3: 208-216.

Maggio, C.A., Pi-Sunyer (1997) The Prevention and Treatment of Obesity: Application to Type 2 Diabetes. *Diabetes Care*, 20: 1744-1766.

Manuel, D.G., Schultz, S.E (2004) Health-Related Quality of Life and Health Adjusted Life Expectancy of People with Diabetes in Ontario, Canada, 1996-1997. *Diabetes Care*, 27: 407-414.

Marcus, M. D., Wing, R. R., Guare, Blair, E. H., Jawad. (1992) Lifetime Prevalence of Major Depression and It's Effect on Treatment Outcome in Obese Type II Diabetic Patients. *Diabetes Care*. 15,2: 253-255.

Matthews, D.R., Pramming, S. (2003) Diabetes and the Global Burden of Non-Communicable Disease. *Lancet*, 362: 1763-1764.

Maxwell, A. E., Hunt, I. F., Bush, M. A. (1992) Effects of a Social Support Group, as an Adjunct to Diabetes Training, on Metabolic Control and Psychosocial Outcomes. *The Diabetes Educator*. 18, 4: 303-309.

Mazzuca, S. A., Moorman, N. H., Wheeler, M. L., Norton, J. A., Fineberg, N. S., Vinicor, F., Cohen, S. J., Clark, C. M. (1986) The Diabetes Education Study: A Controlled Trial of the Effects of Diabetes Patient Education. *Diabetes Care*. 9, 1: 1-10.

McConnaughty, E.S., Prochaska, J.O., & Velicier, W.F. (1983) Stages of Change in Psychotherapy: Measurement and Sample Profiles. *Psychotherapy, Theory, Research and Practice*, 20: 318-375.

McKay, H. G., Glasgow, R. E., Feil, E. G., Boles, S. M., Barrera Jr., M. (2002) Internet-Based Diabetes Self-Management and Support: Initial Outcomes from the Diabetes Network Project. *Rehabilitation Psychology*, 47: 31-48.

McKay, H. G., King, D., Eakin, E. G., Seeley, J. R., Glasgow, R. E. (2001) The Diabetes Network Internet-Based Physical Activity Intervention: A Randomized Pilot Study. *Diabetes Care*. 24: 1328-1334.

McKean Skaff, M., Mullan, J.T., Fisher, L, Chesla, C.A. (2003). A Contextual Model of Control Beliefs, Behavior and Health: Latino and European Americans with Type 2 Diabetes. *Psychology and Health*. 18, 3: 295-312.

McKelvey, J. Waller, D.A., North, A.J., Marks, J.F., Schreiner, B., Travis, L.B. & Murphy, J.N. (1993). Reliability and Validity of the Diabetes Family Behavior Scale (DFBS). *Diabetes Educator*, 19: 125-132.

McNair, D.M., Lorr, M., Droppiman, L.F. (1971) *EDITS Manual for the Profile of Mood States*: 1-27. San Diego: Educational & Industrial Testing Service.

McNally, S.T., Newman S. (1999) Objective and Subjective Conceptualizations of Social Support. *Journal of Psychosomatic Research*, 46: 309-314.

Meadows, P. (1995) Variation in Diabetes Mellitus Prevalence in General Practice in Relation to Deprivation. *Diabetic Medicine*, 12: 696-700.

Medical Research Council (2000) A Framework for Development & Evaluation of RCTS for Complex Interventions to Improve Health. www.mrc.ac.uk/pdf-mrc-cpr-pdf.

Meigs, J. B. (2003) The Metabolic Syndrome: May Be A Guidepost of Detour to Preventing Type 2 Diabetes and Cardiovascular Disease. *British Medical Journal,* 327: 61-62.

Miller, C. K., Edwards, L., Kissling, G., Sanville, L. (2002) Nutrition Education Improves Metabolic Outcomes among Older Adults with Diabetes Mellitus: Results from a Randomized Controlled Trial. *Preventive Medicine,* 34: 252-259.

Miller, W.R., Tonigan, J.S. (1996) Assessing Drinkers Motivation for Change: The Stages of Readiness and Treatment Eagerness Scale (SOCRATES) *Psychology, Addiction, Behaviour*, 10: 81-89.

Moher, D., Schulz, K.F., Altman, D.G. for the Consort Group. (2001) The CONSORT Statement: Revised Recommendations for Improving the Quality of Reports of Parallel Group Randomised Trials. *Lancet*, 357: 1191-94

Mokdad, A.H., Ford, E.S., Bowman, B.A., Dietz, W.H., Vinicor, F., Bales, V.S., Marks, J.S. (2003) Prevalence of Obestiy, Diabetes, and Obesity-Related Health Risk Factors, 2001. *JAMA*, 289: 76-79.

Muchmore, D. B., Springer, J., Miller, M. (1994) Self-Monitoring of Blood Glucose in Overweight Type 2 Diabetic Patients. *Acta Diabetologica*. 31: 215-219.

Murata, G.H., Shah, J.H., Hoffman, R.M., Wendel, C.S., Adam, K.D., Solvas, P.A., Bokhari, S.U., Duckworth, W.C. (2003). Intensified Blood Glucose Monitoring Improves Glycemic Control in Stable, Insulin-Treated Veterans with Type 2 Diabetes. The Diabetes Outcomes in Veterans Study (DOVES). *Diabetes Care*. 26, 6: 1759-1763.

Myers, J., Atwood, E. & Froelicher V. (2003) Active Lifestyle and Diabetes. *Circulation*, 107: 2392-2394.

Naqib, J. (2002) *Patient Education for Effective Diabetes Self-Management: Report, Recommendations and Examples of Good Practice.* Diabetes UK, London.

National Institute for Clinical Excellence (2002) *Management of Type 2 Diabetes: Management of Blood Glucose.* Clinical Guideline G. NICE, London.

Nelson, E., Wasson, J., Kirk, J. et al. (1987) Assessment of Function in Routine Clinical Practice: Description of the COOP Chart Method and Preliminary Findings. *Journal of Chronic Disease*, 40: 55S.

Nelson, K.M., Reiber, G., Boyko, E.D.J. (2002). Diet and Exercise Among Adults with Type 2 Diabetes. Findings from the Third National Health and Nutrition Examination Survey (NHANES III). *Diabetes Care*. 25, 10: 1722-1728.

Newham, A., Ryan, R., Khunti, K., Majeed, A. (2002) Prevalence of Diagnosed Diabetes Mellitus in General Practice in England and Wales, 1994 to 1998. *Health Statistics Quarterly*, 14: 5-13.

Newman, S., Steed, L., Mulligan, K. (2004) Self-Management Interventions for Chronic Illness. *Lancet*, 364: 1523-1537.

Nichols, G.A., Brown, J.B. (2003). Unadjusted and Adjusted Prevalence of Diagnosed Depression in Type 2 Diabetes. *Diabetes Care*. 26, 3: 744-749.

Norris, S.L, Nichols, P.J., Caspersen, C.J., Glasgow, R.E., Engelgau M.M. et al. (2002b) Increasing Diabetes Self-Management Education in Community Settings: A Systematic Review. *American Journal of Preventive Medicine*, 22: 39-66.

Norris, S.L., Engelgau, M.M., Venkat Narayan, K.M. (2001) Effectiveness of Self-Management Training in Type 2 Diabetes: A Systematic Review of Randomized Controlled Trials. *Diabetes Care,* 24: 561-587.

Norris, S.L., Lau, J., Smith, S.J., Schmid, C.H., Engelgau, M.M (2002a) Self-Management Education for Adults with Type 2 Diabetes: A Meta-Analysis of the Effect on Glycaemic Control. *Diabetes Care,* 25: 1159-1171.

Nutrition Subcommittee of the Diabetes Care Advisory Committee of Diabetes UK (2003) The Implementation of Nutritional Advice for People with Diabetes. *Diabetic Medicine*, 20: 786-807.

O'Brien, E., Beevers, G., Lip, G.Y.H. (2001). Blood Pressure Measurement. Part IV – Automated Sphygmomanometry: Self Blood Pressure Measurement. *British Medical Review.* 322: 1167-1170.

O'Brien, E., Waeber, B., Parati, G., Staessen, J., Myers, M.G. (2001). Blood Pressure Measuring Devices: Recommendations of the European Society of Hypertension. *British Medical Journal.* 322: 531-536.

O'Connor, P.J., Asche, S.E., Crain, A.L., Rush, W.A., Whitebird, R.R., Solberg, L.I., Sperl-Hillen, J.M. (2004) Is Patient Readiness to Change a Predictor of Improved Glycemic Control? *Diabetes Care*, 27: 2325-2329.

Paddock, L.E., Veloski, J., Chatterton, M.L., Gevirtz, F.O. & Nash, D.B. (2000) Development and Validation of a Questionnaire to Evaluate Patient Satisfaction with Diabetes Disease Management. *Diabetes Care*, 23: 951-956.

Padgett, D., Mumford, E., Hynes, M. & Carter,R. (1988) Meta-Analysis of the Effects of Educational and Psychosocial Interventions on Management of Diabetes Mellitus *Journal of Clinical Epidemiology* 41: 1007-1030.

Palinkas, L.A., Barrett-Connor, E. & Wingard, D.L. (1991) Type 2 Diabetes and Depressive Symtpoms in Older Adults: A Population Based Study. *Diabetic Medicine,* 8: 532-539.

Pascale, R. W., Mullen, M., Wing, R. R., Bononi, P., Butler, B. A. (1995) Effects of a Behavioural Weight Loss Program Stressing Calorie Restriction Versus Calorie Plus Fat Restriction in Obese Individuals with NIDDM or a Family History of Diabetes. *Diabetes Care.* 18, 9: 1241-1248.

Patel, K.A. & Schlundt, D.G. (2001). Impact of Moods and Social Context on Eating Behaviour. *Appetite*, 36: 111-118.

Peel, E., Parry, O., Douglas, M. & Lawton, J. (2004). Blood Glucose Self-Monitoring in Non-Insulin-Treated Type 2 Diabetes: A Qualitative Study of Patients' Perspectives. *British Journal of General Practice*, 54: 183-188.

Penninx, B.W.J.H., van Tilburg, T., Boeke, A.J.P., Deeg, D.J.H., Kriegsman, D.M.W., van Eijk, J.T.M. (1998). Effects of Social Support and Personal Coping Resources on Depressive Symptoms: Different for Various Chronic Diseases? *Health Psychology.* 17, 6: 551-558.

Perry, I.V, Wannamethee, S.G., Walker, M.K, Thomson, A.G., Whincup, P.H. & Shaper, A.G. (1995) Prospective Study of Risk Factors for Development of Non-Insulin Dependent Diabetes in Middle Aged British Men. *British Medical Journal*, 310: 560-564.

Peyrot, M., Rubin, R. R. (1997) Levels and Risks of Depression and Anxiety Symptomatology Among Diabetic Adults. *Diabetes Care.* 20,4: 585-590.

Peyrot, M., & Rubin, R.R. (1999) Persistence of Depressive Symptoms in Diabetic Adults. *Diabetes Care*, 22: 448-452.

Pibernik-Okanovic, M., Prasek, M. Polijicanin-Filipovic, T., Pavlic-Renar, I. Metelko, Z. (2004) Effects of an Empowerment Based Psychosocial Intervention on Quality of Life and Metabolic Control in Type 2 Diabetic Patients. *Patient Education and Counselling*, 52: 93-199

Pickup, J., Williams, G. (Eds) (1997) Textbook of Diabetes. Oxford, Blackwell Science.

Pickup, J. (1997) Diabetic Control and Its Measurement. In Pickup, J. & Williams, G. (Eds) *Textbook of Diabetes Vol.2.* Oxford: Blackwell Science.

Pieber, T. R., Holler, A., Siebenhofer, A., Brunner, G. A., Semlitsch, B., Schattenberg, S., Zapotoczky, H., Rainer, W., Krejs, G. J. (1995) Evaluation of a Structured Teaching and Treatment Programme for Type 2 Diabetes in General Practice in a Rural Area of Austria. *Diabetic Medicine.* 12: 349-354.

Plotnikoff, R.C., Brez, S., Hotz, S.B. (2000). Exercise Behavior in a Community Sample with Diabetes Understanding the Determinants of Exercise Behavioral Change. *The Diabetes Educator.* 26, 3: 450-459.

Pollard, W.E., Bobbitt., R.A., Bergner, M. et al. (1976) The Sickness Impact Profile: Reliability of a Health Status Measure. *Medical Care*, 14: 146

Pouwer, F., Beekman, A.T.F., Nijpels, G., Dekker, J.M., Snoek, F.J., Kostense, P.J., Heine, R.J., Deeg, D.J.H. (2003). Rates and Risks for Co-Morbid Depression in Patients with Type 2 Diabetes Mellitus: Results from a Community-Based Study. *Diabetologia.* 46: 892-898.

Pratt, C., Wilson, W., Leklem, J., Kingsley, L. (1987) Peer Support and Nutrition Education for Older Adults with Diabetes. *Journal of Nutrition for the Elderly.* 6: 31-43.

Prochaska, J.O. & DiClemente, C.C. (1984) *The Transtheoretical Approach: Crossing Traditional Boundaries of Therapy.* Homewood, IL: Dow Jones Irwin.

Prochaska, J.O. (1994) Strong and Weak Principles for Progressing from Precontemplation to Action Based on Twelve Problem Behaviours. *Health Psychology*, 13: 47-51.

Prochaska, J.O., DiClemente, C.C., Norcross, J.C. (1992) In Search of How People Change: Applications to Addictive Behaviours. *American Psychologist,* 47:1102-1114.

Prochaska, J.O., Johnson, S., Lee, P. (1998) The Transtheoretical Model of Behavior Change. In Schron, E.B & Shumaker, S. (Eds) *The Handbook of Health Behavior Change* (2nd Ed): 59-84. New York, US. Springer.

Radloff, L. (1977) The CES-D Scale: A Self-Report Depression Scale for Research in the General Population. *Applied Psychosocial Measurement*, 1: 385-401.

Rajala, U., Keinanen-Kiukaanniemi, S., Kivela, S.L. (1997). Non-Insulin-Dependent Diabetes Mellitus and Depression in a Middle-Aged Finnish Population. *Soc Psychiatry –Psychiatr-Epidemiol.* 32: 363-367.

Rajala, U., Laakso, M., Qiao, Q., Keinanen-Kiukaanniemi S. (1998) Prevalence of Retinopathy in People with Diabetes, Impaired Glucose Tolerance and Normal Glucose Tolerance. *Diabetes Care*, 21: 1664-1669.

Raleigh, V.S., Kiri, V. & Balarajan, R. (1996) Variations in Mortality from Diabetes Mellitus, Hypertension and Renal Disease in England and Wales by Country of Birth. *Health Trends*, 28, 4: 122-127.

Redekop, W.K, Koopmanschap, M.A., Stolk, R.P., Rutten, G.E.H.M., Wolfenbuttei, B.H.R. & Niessen, L.W. (2002) Health-Related Quality of Life and Treatment Satisfaction in Dutch Patients with Type 2 Diabetes. *Diabetes Care*, 25: 458-463.

Rickheim, P. L., Weaver, T. W., Flader, J. L., Kendall, D. M. (2002) Assesment of Group Versus Individual Diabetes Education. *Diabetes Care*, 25: 269-274.

Ridgeway, N. A., Harvill, D. R., Harvill, L. M., Falin, T. M., Forester, G. M., Gose, O. D. (1999) Improved Control of Type 2 Diabetes Mellitus: A Practical Education/Behavior Modification Program in a Primary Care Clinic. *Southern Medical Journal*, 92: 667-672.

Ritz, E., Orth, S.R. (1999) Nephropathy in Patients with Type 2 Diabetes Mellitus. *Primary Care*. 341: 1127-1133.

Roberts, R., Hemingway, H., Marmot, M. (1997). Psychometric and Clinical Validity of the SF-36 General Health Survey in the Whitehall II Study. *British Journal of Health Psychology*. 2: 285-300.

Robison, F. F. (1993) A Training and Support Group for Elderly Diabetics: Description and Evaluation. *The Journal for Specialists in Group Work.* 18: 127-136.

Rose, M., Fliege, H., Hildebrandt, M., Schirop, T., Klapp, B.F. (2002). The Network of Psychological Variables in Patients with Diabetes and Their Importance for Quality of Life and Metabolic Control. *Diabetes Care.* 25, 1; 35-42

Rossi, J.S. (1992) Stages of Change for 15 Health Risk Behaviors in an HMO Population. Paper Presented at 13th Meeting of the Society for Behavioural Medicine, New York, NY.

Rubin, R. R., Peyrot, M., Saudek, C. D. (1991) Differential Effect of Diabetes Education on Self-Regulation and Life-Style Behaviors. *Diabetes Care*. 14: 335-338.

Rubin, R.R., Peyrot, M. (1989) Effect of Diabetes Education on Self-Care, Metabolic Control, and Emotional Well-Being. *Diabetes Care*. 12: 673-679.

Rubin, R.R., Peyrot, M. & Saudek, C.D. (1993) The Effect of a Diabetes Education Program Incorporating Coping Skills Training on Emotional Well-Being and Diabetes Self-Efficacy. *Diabetes Educator*, 19: 210-214.

Rubin, R.R., Peyrot, M. (1999). Quality of Life and Diabetes. *Diabetes Metabolism Research and Reviews.* 15: 205-218.

Ruggiero, L., Glasgow, R.E., Dryfoos, J.M., Rossi, J.S., Prochaska, J.O., Orleans, C.T., Prokhorov, A.V., Rossi, S.R., Greene, G.W., Reed, G.R., Dpharm, K.K., Chobanian, L., Johnson, S. (1997) Diabetes Self-Management. Self-reported Recommendations and Paterns in a Large Population. *Diabetes Care.* 20, 4; 568-576.

Salmon, P. (2000). Effects of Physical Exercise on Anxiety, Depression, and Sensitivity to Stress: A Unifying Theory. *Clinical Exercise Review*, 21: 33-61.

Samaras, K., Ashwell, S., Mackintosh, A. M., Fleury, A. C., Campbell, L. V., Chisholm, D. J. (1997) Will Older Sedentary People with Non-Insulin-Dependent Diabetes Mellitus Start Exercising? A Health Promotion Model. *Diabetes Research and Clinical Practice.* 37, 121-128.

Sarafino, E.P. (1998) Health Psychology: Biopsychosocial Interactions (3rd Ed). Wiley, USA.

Sarason, I.G., Levine, H.M., Basham, R.B. & Sarason, B.R. (1983) Assessing Social Support: The Social Support Questionnaire. *Journal of Personality and Social Psychology,* 44: 127-139.

Sarkadi, A., Rosenqvist, U. (2001) Field Test of a Group Education Program for Type 2 Diabetes: Measures and Predictors of Success on Individual and Group Levels. *Patient Education and Counseling.* 44: 129-139.

Schafer L, McCaul, K. D., Glasgow, R.E. (1986) Supportive and Non-Supportive Family Behaviors: Relationships to Adherence and Metabolic Control in Persons with Type I Diabetes. *Diabetes Care*, 9: 179-185.

Schneider, S. H., Ruderman, N. B. (1990). Exercise and NIDDM. *Diabetes Care.* 13, 7:785-789.

Schwarzer, R., Leppin A. (1991) Social Support and Health: A Theoretical and Empirical Overview. *Journal of Social and Personal Relationships.* 8: 99-127.

Schwedes, U.I, Siebolds, M., Mertes, G., For the SMBG Study Group. (2002). Meal-Related Structured Self-Monitoring of Blood Glucose. *Diabetes Care.* 25, 11: 1928-1932.

Senecal, C., Nouwen, A., White, D. (2000). Motivation and Dietary Self-Care in Adults with Diabetes: Are Self-Efficacy and Autonomous Self-Regulation Complementary or Competing Constructs? *Health Psychology.* 19, 5; 452-457.

Sigal, R.J., Kenny, G.P., Wasserman, D.H., Castenada-Sceppa, C. (2004). Physical Actiivty/Exercise and Type 2 Diabetes. *Diabetes Care*, 27: 2518-2539.

Simpson, R.W., Shaw J.E., Zimmet, P.Z. (2003) The Prevention of Type 2 Diabetes – Lifestyle Change or Pharmacotherapy? A Challenge for the 21st Century. *Diabetes Research and Clinical Practice*, 59: 175-180.

Sinclair, V.G., Wallston, K.A. (2001) Predictors of Improvement in a Cognitive-Behavioral Intervention for Women with Rheumatoid Arthritis. *Annals of Behavioral Medicine.* 23: 291-297.

Skelly, A.H., Marshall, J.R., Haughey, B.P., Davis, P.J., Dunford, R.G. (1995). Self-Efficacy and Confidence in Outcomes as Determinants of Self-Care Practices in Inner-City, African-American Women with Non-Insulin-Dependent Diabetes. *The Diabetes Educator.* 21, 1; 38-46.

Smith, D. E., Heckemeyer, C. M., Kratt, P. P., Mason, D. (1997) A. Motivational Interviewing to Improve Adherence to a Behavioural Weight-Control Program for Older Obese Women with NIDDM. *Diabetes Care.* 20,1: 52-54.

Speight, J., Bradley, C. (2001) The ADKNOWL: Identifying Knowledge Deficits in Diabetes Care. *Diabetic Medicine*, 18: 626-633.

Spielberger, C.D., Gorsuch, R.L. & Lushene, R.E. (1970) *Manual for the State-Treat Anxiety Inventory.* Palo Alto, CA: Consulting Psychologists Press.

Steed, L., Cooke, D., Newman, S. (2003) A Systematic Review of Psychosocial Outcomes Following Education, Self-Management and Psychological Interventions in Diabetes Mellitus. *Patient Education and Counselling*, 51: 5-15.

Steptoe, A., Lipsey, Z. & Wardle J. (1998). Stress, Hassles and Variations in Alcohol Consumption, Food Choice and Physical Activity: A Diary Study. *British Journal of Health Psychology*, 3: 51-63.

Stewart, A.L., Ware, J.E. (1992) *Measuring Functioning and Well-Being: The Medical Outcomes Study Approach.* Duke Press: London.

Stratton, I.M., Adler, A.I., Neil, H.A.W., Matthews, D.R., Manley, S.E., Cull, C.A., Hadden, D., Turner, R.C., Holman, R.R. on behalf of the UK Prospective Diabetes Study Group. (2000). Association of Glycaemia with Macrovascular and Microvascular Complications of Type 2 Diabetes (UKPDS 35): Prospective Observational Study. *British Medical Journal.* 321: 405-412.

Surwit, R. S. & Feinglos, M. N. (1983) The Effects of Relaxation on Glucose Tolerance in Non-insulin-dependent Diabetes. *Diabetes Care.* 6, 2: 176-179.

Surwit, R. S., van Tilburg, M. A., Zucker, N., McCaskill, C. C., Parekh, P., Feinglos, M. N., Edwards, C. L., Williams, P., Lane, J. D. (2002) Stress Management Improves Long-Term Glycemic Control in Type 2 Diabetes. *Diabetes Care.* 25,1: 30-34.

Sutton, S. (2000) A Critical Review of the Transtheoretical Model Applied to Smoking Cessation. In Norman, P., Abraham, C., & Conner, M. (Eds). *Understanding and Changing Health Behaviour: From Health Beliefs to Self-Regulation.* Amsterdam: Harwood.

Sutton, S. (2000) A Critical Review of the Transtheoretical Model Applied to Smoking Cessation. In Abraham, C. & Norman, P. (Eds) Understanding & Changing Health Behaviour: From Health Beliefs to Self-Regulation: 207-225. Amsterdam, Netherlands, Harwood.

Tabachnick, B.G. & Fidell, L.S. (1996) Using Multivariate Statistics (3rd Ed.) New York. Harper Collins

Talbot, F., Nouwen, A. (2000). A Review of the Relationship Between Depression and Diabetes in Adults. *Diabetes Care*. 23, 10: 1556-1562.

Talbot, F., Nouwen, A., Gingras, J., Gosselin, M., Audet. (1997). The Assessment of Diabetes-Related Cognitive and Social Factors: The Multidimensional Diabetes Questionnaire. *Journal of Behavioral Medicine*. 20, 3: 291-312.

Tanasescu, M., Leitzmann, M.F., Rimm, E.B. (2003). Physical Activity in Relation to Cardiovascular Disease and Total Mortality Among Men with Type 2 Diabetes. *Circulation*, 107: 2435-2439.

Targher, G., Alberiche, M., Zenere, M., Bonadonna, R., Muggeo, M. & Bonora, E. (1997). Cigarette Smoking and Insulin Resistance in Patients with Non-Insulin-Dependent Diabetes Mellitus. *Journal of Clinical and Endocrinology Metabolism*, 82: 3619-3624.

TenHave, T.R., Coyne, J., Salzer, M. & Katz, I. (2003) Research to Improve the Quality of Care for Depression: Alternatives to the Simple Randomized Clinical Trial. *General Hospital Psychiatry*, 25: 115-123.

The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus (1998) Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care*, 21, S1: 1-21.

Thomas, J., Jones, G., Scarinci, E., Brantley, P. (2003). A Descriptive and Comparative Study of the Prevalence of Depressive and Anxiety Disorders in Low-Income

Adults with Type 2 Diabetes and Other Chronic Illnesses. *Diabetes Care*. 26, 8: 2311-2317.

Tillotson, L. M., Smith, S. (1996). Locus of Control, Social Support, and Adherence to the Diabetes Regimen. *The Diabetes Educator*. 22, 2: 133-139.

Toobert, D. J., Glasgow, R. E., Strycker, L. A., Barrera Jr, M., Radcliffe, J. L., Wander, R. C., Bagdade, J. D. (2003) Biologic and Quality-of-Life Outcomes from the Mediterranean Lifestyle Program. 26, 8: 2288-2293.

Toobert, D.J., Glasgow, R.E. (1991). Problem Solving and Diabetes Self-Care. *Journal of Behavioral Medicine*. 14, 1; 71-86

Toobert, D.J., Hampson, S.E., Glasgow, R.E. (2000) The Summary of Diabetes Self-Care Activities Measure: Results from Seven Studies and a Revised Scale. *Diabetes Care,* 23: 943-949.

Toobert, D.J., Strycker, L.A., Glasgow, R.E., Bagdade, J.D. (2002). If You Build It, Will They Come? Reach and Adoption Associated with a Comprehensive Lifestyle Management Program for Women with Type 2 Diabetes. *Patient Education and Counseling*. 1646: 1-7.

Trafimow, D., Sheeran, P., Conner, M. & Finlay, K.A. (2002) Evidence That Perceived Behavioral Control is a Multidimensional Construct: Perceived Control and Perceived Difficulty. *British Journal of Social Psychology*, 41: 101-121.

Trento, M., Passera, P., Bajardi, M., Tomalino, M., Grassi, G., Borgo, E., Donnola, C., Cavallo, F., Bondonio, P., Porta, M. (2002) Lifestyle Intervention by Group Care Prevents Deterioration of Type 11 Diabetes: A 4-Year Randomized Controlled Clinical Trial. *Diabetologia*, 45: 1231-12399.

Trento, M., Passera, P., Borgo, E., Tomalino, M., Bajardi, M., Cavallo, F. & Porta, M. (2004) A 5-Year Randomized Controlled Study of Learning, Problem Solving

Ability, and Quality of Life Modifications in People with Type 2 Diabetes Managed by Group Care. *Diabetes Care,* 27: 670-675.

Trento, M., Passera, P., Tomalino, M., Bajardi, M., Pomero, F., Allione, A., Vaccari, P., Molinatti, GM. & Porta, M. (2001) Group Visits Improve Metabolic Control in Type 2 Diabetes: A 2 Year Follow-Up. *Diabetes Care.* 24: 995-1000.

Trento, M., Passera, P., Tomalino, M., Pagnozzi, F., Pomero, F., Vaccari, P., Bajardi, M., Molinatti, G. M., Porta, M. (1998) Therapeutic Group Education in the Follow-Up of Patients with Non-Insulin Treated, Non-Insulin Dependent Diabetes Mellitus. *Diabetes Nutrition and Metabolism.* 11, 3: 212-215.

Trigwell, P., Grant, P.J., House, A. (1997). Motivation and Glycemic Control in Diabetes Mellitus. *Journal of Psychosomatic Research.* 43, 3; 307-315.

Tuomilehto J, Lindstrom J, Eriksson JG, Valle TT, Hamalainen H, Ilanne-Parikka P, Keinanen-Kiukaanniemi S, Laakso M, Louheranta A, Rastas M, Salminen V, Uusitupa M (2001) Prevention of Type 2 Diabetes Mellitus by Changes in Lifestyle Among Subjects with Impaired Glucose Tolerance. *New England Journal of Medicine* 344: 1343-1350.

Tudor-Locke, C.E., Myers A.M., Bell, R.C., Harris, S.B. & Rodger, N.W. (2002) Preliminary Outcome Evaluation of the First Step Program: A Daily Physical Activity Intervention for Individuals with Type 2 Diabetes. *Patient Education & Counseling*, 47: 23-28.

UK Prospective Diabetes Study (UKPDS) Group (1998a) Intensive Blood Glucose Control with Sulphonylureas or Insulin Compared with Conventional Treatment and Risk of Complications in Patients with Type 2 Diabetes (UKPDS 33). *Lancet*, 352: 837-853.

UK Prospective Diabetes Study (UKPDS) Group. (1998b). Effect of Intensive Blood-Glucose Control with Metformin on Complications in Overweight Patients with Type 2 Diabetes (UKPDS 34). *The Lancet.* 352, 9131: 854-865.

UK Prospective Diabetes Study (UKPDS) Group. (1999). Quality of Life in Type 2 Diabetic Patients is Affected by Complications But Not by Intensive Policies to Improve Blood Glucose or Blood Pressure Control (UKPDS 37). *Diabetes Care*, 22: 1125-1136.

UK Prospective Diabetes Study Group. (1998c). Tight Blood Pressure Control and Risk of Macrovascular and Microvascular Complications in Type 2 Diabetes: UKPDS 38. *British Medical Journal.* 317: 703-713.

Ulbig, M.R.W., Hamilton, A.M.P (1993) Factors Influencing the Natural History of Diabetic Retinopathy. *Eye*, 17: 242-249.

Vallis, M., Ruggiero, L., Greene, G., Jones, H., Zinman, B., Rossi, S., Edwards, L., Rossi, J.S., Prochaska, J.O. (2003). Stages of Change for Healthy Eating in Diabetes. *Diabetes Care.* 26, 5; 1468-1474.

Vazquez, I. M., Millen, B., Bissett, L., Levenson, S. M., Chipkin, S. R. (1998) Buena Alimentacion, Buena Salud: A Preventive Nutriition Intervention in Caribbean Latinos with Type 2 Diabetes. *American Journal of Health Promotion*, 13: 116-119.

Venkat Narayan, K.M., Boyle, J.P., Thompson, T.J., Sorensen, S.W. & Williamson, D.F. (2003) Lifetime Risk for Diabetes Mellitus in the United States. *JAMA*, 290, 14: 1884-1890.

Via, P.S., Salyer, J. (1999). Psychosocial Self-Efficacy and Personal Characteristics of Veterans Attending a Diabetes Education Program. *The Diabetes Educator.* 25, 5; 727-737.

Vincze, G., Barner, J.C., Lopez, D. (2004). Factors Associated with Adherence to Self-Monitoring of Blood Glucose Among Persons with Diabetes. *The Diabetes Educator.* 30, 1: 112-125.

Von Korff, M., Glasgow, R.E., Sharpe, M. (2002). ABC of Psychological Medicine. Organising Care for Chronic Illness. *British Medical Journal.* 325: 92-94.

Wagner, E.H. (1998) Chronic Disease Management: What Will it Take to Improve Care for Chronic Illness? *Effective Clinical Practice*, 1: 2-4.

Wagner, E.H. (2004). Chronic Disease Care. Insights from Managed Care in the United States will Help the NHS. *British Medical Journal.* 328: 177-178.

Wallston, K.A., Wallston, B.S. & DeVellis, R. (1978) Development of the Multidimensional Health Locus of Control (MHLC) Scales. *Health Education Monographs*, 6: 160-170.

Wandell, P.E., Tovi, J. (2000). The Quality of Life of Elderly Diabetic Patients. *Journal of Diabetes and Its Complications.* 14: 25-30.

Wang, C-Y., Fenske, M.M. (1996). Self-Care of Adults with Non-Insulin-Dependent Diabetes Mellitus: Influence of Family and Friends. *The Diabetes Educator.* 22, 5: 465-470.

Ware J.H., Sherbourne, C.D. (1992) The MOS 36-Item Short Form Health Survey (SF-36). I. Conceptual Framework and Item Selection. *Medical Care*, 30: 473-483.

Washburn, R.A., Smith, K.A., Jette., A.M. & Janney, C.A. (1993) The Physical Activity Scale for the Elderly (PASE): Development and Evaluation. *Journal of Clinical Epidemiology,* 46: 153-162.

Watkins, K.W., Connell, C.M., Fitzgerald, J.T., Klem, L., Hickey, T., Ingersoll-Dayton, B. (2000). Effect of Adults' Self-Regulation of Diabetes on Quality-of-Life Outcomes. *Diabetes Care.* 23, 10: 1511.

Watson, D., Clark, L.A. & Tellegen, A. (1988). Development and Validation of Brief Measures or Positive and Negative Affect: The PANAS Scales. *Journal of Personality and Social Psychology*, 54, 1063-70.

Weinman, J., Petrie., K.J., Moss-Morris, R. & Horne, R. (1996) The Illness Perception Questionnaire: A New Method for Assessing the Cognitive Representations of Illness. *Psychology and Health*, 11: 431-444.

Weinstein, N.D. (1988) The Precaution Adoption Process. *Health Psychology*, 14: 132-140.

Welch, G. & Smith, R. B. W. (1992) The Evaluation of a Behavioural Food and Weight Control Programme for Obese Patients with Noninsulin Dependent Diabetes. 105: 9-10.

Weyerer, S., Hewer, W., Pfeifer-Kurda, M., Dilling, H. (1989). Psychiatric Disorders and Diabetes: Results From a Community Study. *Journal of Psychosomatic Research*, 33: 633-640.

White, N., Carnahan, J., Nugent, C. A., Iwaoka, T., Dodson, M. A. (1986) Management of Obese Patients With Diabetes Mellitus: Comparision of Advice Education With Group Management. *Diabetes Care*. 9 5:. 490-496.

Whitfield, K.E., Clark, R., Weidner, G. & Anderson, N.B. (2002) Sociodemographic Diversity and Behavioral Medicine. *Journal of Consulting and Clinical Psychology*, 70, 3: 463-481.

Wierenga, M. E. (1994) Life-style Modification for Weight Control to Improve Diabetes Health Status. *Patient Education and Counseling*. 23: 33-40.

Wild, S., Roglic, G., Green, A., Sicree, R., King, H. (2004) Global Prevalence of Diabetes: Estimates for the Year 2000 and Projections for 2030. *Diabetes Care*, 27, 5: 1047-1053.

Willet, L.L., & Albright, E.S. (2004) Achieving Glycemic Control in Type 2 Diabetes: A Practical Guide for Clinicians on Oral Hypoglycemics. *Southern Medical Association*, 97, 11: 1088-1092.

Williams, K.E. & Bond, M.J. (2002). The Roles of Self-Efficacy, Outcome Expectancies and Social Support in the Self-Care Behaviours of Diabetics. *Psychology, Health & Medicine*. 7, 2; 128-141.

Williams, R., Wild, S. (2003) Diabetes Prevalence Data for the United Kingdom – What Do We Have and What Do We Need? *Diabetic Medicine*, 20: 505.

Willoughby, D.F., Kee, C.C., Demi, A., Parker, V. (2000). Coping and Psychosocial Adjustment of Women With Diabetes. *The Diabetes Educator.* 26, 1: 105-112.

Wilson, W., Ary, D.V., Biglan, A., Glasgow, R.E., Toobert, D.J., Campbell, D.R. (1986) Psychosocial Predictors of Self-Care Behaviors (Compliance) and Glycemic Control in Non-Insulin-Dependent Diabetes Mellitus. *Diabetes Care*. 9, 6; 614-622.

Wing RR. (2002) Weight Loss in the Management of Type 2 Diabetes. In *Evidence Based Diabetes Care*. Gerstein, H.C., Haynes, R.B. (Eds). Hamilton, Ontario, Canada, B.C. Decker.

Wing, R. R., Epstein, L. H., Nowalk, M. P., Scott, N., Koeske, R., Hagg, S. (1986) Does Self-Monitoring of Blood Glucose Levels Improve Dietary Compliance for Obese Patients with Type II Diabetes? *The American Journal of Medicine.* 81: 830-836.

Wing, R. R., Epstein, L. H., Paternostro-Bayles, M., Kriska, A., Nowalk, M. P., Gooding, W. (1988) Exercise in a Behavioural Weight Cotrol Programme for Obese Patients with Type 2 (Non-Insulin-Dependent) Diabetes. *Behavior Therapy*, 31: 902-909.

Wing, R. R., Marcus, M. D., Blair, E. H., Burton, L. R. (1991a) Psychological Responses to Obese Type II Diabetic Subjects to Very-Low-Calorie Diet. *Diabetes Care.* 14, 7: 596-599.

Wing, R. R., Marcus, M. D., Epstein, L. H., Jawad, A. (1991b) A "Family-Based" Approach to the Treatment of Obese Type II Diabetic Patients. *Journal of Consulting and Clinical Psychology.* 59, 1: 156-162.

Woodcock, A.J., Julious, S.A., Kinmonth, A.L., Campbell, M.J. (2001). Problems with the Performance of the SF-36 Among People with Type 2 Diabetes in General practice. *Quality of Life Research.* 10: 661-670.

Wooldridge, K. L., Wallston, K. A., Graber, A. L., Brown, A. W., Davidson, P. (1992) The Relationship Between Health Beliefs, Adherence, and Metabolic Control of Diabetes. *The Diabetes Educator.* 18, 6: 495-501.

World Health Organisation (1999) Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications, Part 1, Diagnosis and Classification of Diabetes Mellitus. Geneva: WHO

Wredling,R., Stalhammar,J., Adamson,U., Berne,C., Larsson,Y., Ostman,J. (1995) Well-Being and Treatment Satisfaction in Adults with Diabetes: A Swedish Population-Based Study. *Quality of Life Research*, 4: 515-522.

Wright. L, Harwood, D. & Coulter, A. (1992). Health and Lifestyles in the Oxford Region. Oxford: Health Services Research Unit, University of Oxford,

Zettler, A., Duran, G., Waadt, S., Herschbach, P., Strian, F. (1995) Coping with Fear of Long-Term Complications in Diabetes Mellitus: A Model Clinical Program. *Psychotherapy and Psychosomatics.* 64:. 178-184.

Zigmond, A.S., Snaith, R.P. (1983). The Hospital Anxiety and Depression Scale. *Acta Psychiatr. Scand.* 67: 371-377.

Zimet, G.D., Dahlen, N.W., Zimet, S.F., Farley, G.K. (1988). The Multidimensional Scale of Perceived Social Support. *Journal of Personality Assessment.* 52, 1: 30-41.

APPENDIX ONE

RECRUITMENT INFORMATION

Patient Information Sheet

An invitation to take part in research

"Focus Group Study for Individuals with Type 2 Diabetes"

Investigators: Prof S. Newman, Dr R. Wolfson, Dr K. Earle, Liz Steed

Purpose of the Study?

Adult onset diabetes is the most common form of diabetes. It is affecting an increasing number of people in the UK. Management of diabetes is complex. It includes taking medication, following diet and exercise advice and measuring blood glucose levels. It is not surprising that many patients find it difficult to follow this advice at times. We would like to talk to you about how you find living with diabetes. We would then like to use this information to help us design a self-management programme for people with diabetes.

What will happen?

You will be asked to take part in a focus group which will take approximately 1 hour. This will take place at the hospital. Your permission will be asked to tape-record the focus group to allow for analysis, however all information provided will be completely confidential.

Discomfort and Risks

It is not expected that the focus group will cause any discomfort or risk to participants, rather it is expected that you will find the experience enjoyable.

Confidentiality of Focus Group

The information collected during the study will be confidential. Only the researcher will know that the information is related to you.

Please Note

You do not have to take part in this study if you do not want to but your participation will be much appreciated and we hope you would find the group both enjoyable and beneficial. If you do decide to take part you may withdraw at any time without having to give a reason. Your decision to take part will not affect your care or management in any way.

IF YOU HAVE ANY QUESTIONS OR WOULD LIKE FURTHER INFORMATION PLEASE CONTACT LIZ STEED (0171- 504- 9421).

Confidential

CONSENT FORM

" Focus Group Study for Individuals with Type 2 Diabetes"

Investigators: Prof S. Newman, Dr R. Wolfson, Dr K. Earle, Liz Steed

You have been invited to take part in a focus group to help us understand how people find living with diabetes.

We would like to ask your permission for us to tape record this session.

To be completed by participant:

Delete as necessary

Have you read the patient information sheet? YES/NO

Do you agree to take part in this study? YES/NO

Do you understand that you are free to withdraw from this study
- at any time
- without giving a reason for withdrawing
- without affecting your future medical care?

YES/NO

Signed: ..... Date: .....

Name in Block Letters: .....

Doctor: .....

Patient Information Sheet

An invitation to take part in research

" The Evaluation of a Self-Management Programme for Type 2 Diabetes"

Investigators: Prof S. Newman, Dr R. Wolfson, Dr Earle, Liz Steed

Purpose of the Study?

Adult onset diabetes is the most common form of diabetes. It is affecting an increasing number of people in the UK. Management of diabetes is complex. It includes taking medication, following diet and exercise advice and measuring blood glucose levels. It is not surprising that many patients find it difficult to follow this advice at times. The purpose of this study is to design a programme that will help you follow such advice. It will teach you information and skills about your diabetes and we will discuss your feelings about having diabetes. We will also teach you problem solving techniques for living with diabetes. We hope this will make fitting diabetes care into your daily life an easier task.

What will happen?

The programme itself will be for 2.5 hours, once a week for five weeks. These sessions will be held in small groups with other similar people who have diabetes. There will also be one extra session at 3 months to reflect on what was learnt at earlier sessions. Although we would like you to commit to coming to all 6 sessions it is up to you whether you come alone or bring a partner or friend. If you do decide to take part in the study you will either be allocated to a group straight away or will be asked to complete the assessments described below and be allocated to a group in 9 months time.

The assessments will involve a series of questionnaires. These will ask about how you feel, and how you think your diabetes affects your life in general. All questionnaires will be treated in the strictest confidence. These will be completed in the week before the programme and a researcher will be on hand to answer any questions you may have when completing the questionnaires. In addition we would like to measure your blood pressure and take a blood test, however where possible we will combine this with your clinic visits to reduce the number of tests you need. Assessments will also be

completed after the programme finishes and 3 and 9 months later. This will allow us to see how things may have changed for you since taking part in the study. For all assessments we will try and arrange them at a time most convenient for you. Ideally this will be before or after one of your routine clinic visits but if any additional trips need to be made your travel expenses will then be provided. Alternatively, the researcher can visit you at your home if this is your preference.

Discomfort and Risks

It is not expected that the study will cause any discomfort or risk to participants, rather it is expected that you will find the programme both beneficial and enjoyable.

Confidentiality of Records

We need your permission to access the parts of the records that relate to the study. You are assured of complete confidentiality in all information you may give. The information collected during the study, except your name, will be stored and analysed confidentially in a computer. Only the researcher will know that the information is related to you. The results of this study may be published in the medical literature, however your name and details will not be revealed.

Please Note

You do not have to take part in this study if you do not want to but your participation would be much appreciated and we hope you would find the programme both enjoyable and beneficial. If you do decide to take part you may withdraw at any time without having to give a reason. Your decision to take part will not affect your care or management in any way.

IF YOU HAVE ANY QUESTIONS OR WOULD LIKE FURTHER INFORMATION

PLEASE CONTACT LIZ STEED (020- 7679- 9421)

Confidential

CONSENT FORM

" The Evaluation of a Self-Management Programme for Type 2 Diabetes"

Investigators: Prof S. Newman, Dr R. Woolfson, Dr Earle
Liz Steed

Further Information: Liz Steed (020-7679-9421)

To be completed by participant:

	Delete as necessary
1. Have you read the information sheet?	YES/NO
2. Have you had an opportunity to ask questions and discuss the study?	YES/NO
3. Have you received satisfactory answers to all your questions?	YES/NO
4. Have you received enough information about this study?	YES/NO
5. Which doctor have you spoken to about this study?	.....
6. Do you understand that you are free to withdraw from this study * at any time * without giving a reason for withdrawing ♦ without affecting your future medical care?	YES/NO
7. Do you agree to take part in this study?	YES/NO

Signed: ..... Date: .....

Name in Block Letters:
.....

Doctor: .....

Information for Doctors Recruiting Participants to the Diabetes Self-Management Study

Doctor's Role

- The Doctor will be the first person to approach the patient and suggest the self-management programme research project. The potential benefits of the programme should be raised as well as requirement of individual.
- Need to recruit patients with both good and poor control. Those which have good control may still benefit. They may find ways to make living with their diabetes easier. Also may influence behaviours, which act separately of just blood glucose control, e.g. reduce chances of heart disease.
- As a general rule it is best to introduce the idea to everyone who fulfils the inclusion criteria and the research fellow can go through the formal information giving and consenting process. Judgements about individual's suitability should not be made, outside of the inclusion/exclusion criteria.
- Need to transfer the message that the patient won't be judged for poor control.
- State that whether they take part in research project or not won't affect their care.

Research Fellow's Role

- If patient agrees to discuss project further refer to the research fellow who will describe the project in more detail and consent as applicable.

Programme Aims and Techniques

- The principal aim of the programme is to encourage patients to see their role in caring for their diabetes and give them skills with which they can do this.
- We hope this will improve their blood glucose and blood pressure control, but equally importantly we aim to increase the feeling of control they have over their diabetes.
- The programme is going to be facilitated b a nurse. It will be non-judgemental and accepting that it is difficult to live with diabetes.
- It will be held with other people having similar problems and facing similar difficulties, the hope it that people will be able to help each other in suggesting solutions to problems that they have found.

Doctor's Recruitment Schedule

The following points should be to covered when introducing the self-management project to a patient

- We're developing a self-management programme for individuals with type 2 diabetes (your type of diabetes) and microalbuminuria
- We think this sort of programme could be valuable for people like yourself.
- It's because we know that following advice about diabetes can be difficult.
- We want to help you find ways to make living with diabetes easier.
- This is especially important at this stage, when you are showing early signs of complications.
- By the end of the programme we hope that not only will your blood sugars have improved but also you will be able to solve some of the problems that make living with diabetes difficult.
- Most people who do these sort of programmes find them enjoyable and get a lot out of them.
- The current programme is still new however so it is part of a research study.
- This means you'll be asked to complete some questionnaires before and after the programme.
- If you're interested in this project our research fellow – Liz Steed can spend more time explaining what is involved.
- Whether you decide to take part however won't affect your normal treatment in any way.

Additional points in case patient asks

- The programme will be for a couple of hours, once a week, for 5 weeks
- Patients can choose whether to come alone or bring a partner

APPENDIX TWO

STUDY QUESTIONNAIRES

Questionnaire Instructions

The following questions ask you about both your diabetes and your everyday activities. By answering the questions it will help us to understand your experience of having diabetes and how this influences your day to day life. All the information that you provide will be strictly confidential and will only be seen by the research assistant running the study.

Please read each question carefully and then answer by circling the response that is closest to your situation. You should work through the questions quite quickly and not spend too long on any one question. Remember that there are no right or wrong answers to the questions. If you are unsure about how to answer a question please give the best answer you can. This will allow us to have the most accurate picture of your experiences of having diabetes. Please do not leave any questions blank.

It is also important that you complete the questionnaire on your own without input from family and friends. If you do have any queries about specific questions or would like some assistance to complete the questionnaire please feel free to call Liz Steed on 020-7679- 9421.

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE
Liz Steed (020- 7679-9421)

The following is a short quiz about things related to living with diabetes. After each question there are several possible answers. For all the questions only one answer is correct. Please look at the possible options and decide which option is correct, then mark this option by circling it.

1. The diabetes diet is:
a. the way most British people eat
b. a healthy diet for most people
c. too high in carbohydrate for most people
d. too high in protein for most people

2. Which of the following is highest in carbohydrate?
a. Baked Chicken
b. Swiss Cheese
c. Baked Potato
d. Peanut Butter

3. Which of the following is highest in fat?
a. Low fat milk
b. Orange juice
c. Corn
d. Honey

4. Which of the following is a "free food"
a. Any unsweetened food
b. Any dietetic food
c. Any food that says "sugar free" on the label
d. Any food that has less than 20 calories per serving

5. Which is the best method for testing blood glucose
a. Urine testing
b. Blood testing
c. Both are equally good

6. What effect does unsweetened fruit juice have on blood glucose?
a. Lowers it
b. Raises it
c. Has no effect

7. Eating foods lower in fat decreases your risk for:
a. nerve disease
b. kidney disease
c. heart disease
d. eye disease

8. Which should not be used to treat low blood glucose?
a. 3 hard sweets
b. 1/2 cup orange juice
c. 1 cup diet soft drink
d. 1 cup skimmed milk

9. For a person in good control, what effect does exercise have on blood glucose?
a. Lowers it
b. Raises it
c. Has no effect

10. Glycosylated haemoglobin (HbA1c) is a test that is a measure of your average blood glucose level for the past:
a. day
b. week
c. 6-10 weeks
d. 6 months

11. The best way to take care of your feet is to:
a. look at and wash them each day
b. massage them with alcohol each day
c. soak them for one hour each day
d. buy shoes a size larger than usual

12. Infection is likely to cause:
a. an increase in blood glucose
b. decrease in blood glucose
c. no change in blood glucose

13. Numbness and tingling may be symptoms of:
a. kidney disease
b. nerve disease
c. eye disease
d. liver disease

14. Which of the following is usually not associated with diabetes:
a. vision problems
b. kidney problems
c. nerve problems
d. lung problems

The following questions ask about your quality of life and the effects of your diabetes on your quality of life. Your quality of life is how good or bad you feel your life to be. Please circle the answer which best indicates your response on each scale.

There are no right or wrong answers, we just want to know how you feel about your life now.

A) In general, my present quality of life is:

as good as it could possibly be	very good	good	neither good nor bad	bad	very bad	as bad as it could possibly be

For the next statement, please consider the effects of your diabetes, its management and any complications you may have.

B) If I did not have diabetes, my quality of life would be:

very much better	much better	a little better	the same	a little worse	much worse	very much worse

For each of the following 13 statements please consider the effects of your diabetes, its management and any complications you may have on the aspect of life described by the statement.

In each of the following boxes:

a) Circle the answer that shows how diabetes affects this aspect of your life

b) Circle the answer that shows how important this aspect of your life is to your quality of life

Some statements have a "not applicable " option. Please circle the N/A box if this aspect of life does not apply to you.

1. If I did not have diabetes, my working life and work-related opportunities would be:

very much better	much better	a little better	the same	a little worse	much worse	very much worse	N/A
This aspect of my life is *(please circle the answer that applies to you)*							
very important		important		somewhat important		not at all important	

2. If I did not have diabetes, my social life would be:

very much better	much better	a little better	the same	a little worse	much worse	very much worse
This aspect of my life is *(please circle the answer that applies to you)*						
very important	important	somewhat important	not at all important			

3. If I did not have diabetes my family life would be:

very much better	much better	a little better	the same	a little worse	much worse	very much worse	N/A
This aspect of my life is *(please circle the answer that applies to you)*							
very important	important	somewhat important	not at all important				

4. If I did not have diabetes, my friendships would be:

very much better	much better	a little better	the same	a little worse	much worse	very much worse
This aspect of my life is *(please circle the answer that applies to you)*						
very important	important	somewhat important	not at all important			

5. If I did not have diabetes, my sex life would be:

very much better	much better	a little better	the same	a little worse	much worse	very much worse	N/A
This aspect of my life is *(please circle the answer that applies to you)*							
very important	important	somewhat important	not at all important				

6. If I did not have diabetes, my holidays or leisure activities would be:

very much better	much better	a little better	the same	a little worse	much worse	very much worse
This aspect of my life is *(please circle the answer that applies to you)*						
very important	important	somewhat important	not at all important			

7. If I did not have diabetes, problems with travelling (either local or long distance) would be:

very much decreased	Much decreased	a little decreased	the same	a little increased	much increased	very much increased
This aspect of my life is *(please circle the answer that applies to you)*						
very important	important	somewhat important	not at all important			

8. If I did not have diabetes, my worries about my future (e.g. health, independence, income) would be:

very much decreased	much decreased	a little decreased	the same	a little increased	much increased	very much increased
This aspect of my life is *(please circle the answer that applies to you)*						
very important	important	somewhat important	not at all important			

9. If I did not have diabetes, my worries about the future of my family and close friends (e.g. their health, independence, income) would be:

very much decreased	much decreased	a little decreased	the same	a little increased	much increased	very much increased	N/A
This aspect of my life is *(please circle the answer that applies to you)*							
very important	important	somewhat important	not at all important				

10. If I did not have diabetes my motivation to achieve things would be:

very much increased	much increased	a little increased	the same	a little decreased	much decreased	very much decreased
This aspect of my life is *(please circle the answer that applies to you)*						
very important	important	somewhat important	not at all important			

11. If I did not have diabetes, the things I could do physically would be:

very much increased	much increased	a little increased	the same	a little decreased	much decreased	very much decreased
This aspect of my life is *(please circle the answer that applies to you)*						
very important	important	somewhat important	not at all important			

12. If I did not have diabetes, the extent to which people would fuss or worry about me too much would be:

very much decreased	much decreased	a little decreased	the same	a little increased	much increased	very much increased
This aspect of my life is *(please circle the answer that applies to you)*						
very important	important	somewhat important	not at all important			

13. If I did not have diabetes, my enjoyment of food would be:

very much increased	much increased	a little increased	the same	a little decreased	much decreased	very much decreased
This aspect of my life is *(please circle the answer that applies to you)*						
very important	important	somewhat important	not at all important			

The questions below ask you about your diabetes self-care activities ***during the past 7 days***. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick. Please circle the answer that best reflects your response to each question

Diet

1) How many of the last SEVEN DAYS have you followed a healthful eating plan?

0 1 2 3 4 5 6 7

2) On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?

0 1 2 3 4 5 6 7

3) On average, over the past week, how many pieces of fruit did you eat per day?

0 1 2 3 4 5 6 7+

4) On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?

0 1 2 3 4 5 6 7

5) On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?

0 1 2 3 4 5 6 7

Exercise

6) On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical exercise? (Total minutes of continuous activity, including walking).

0 1 2 3 4 5 6 7

7) On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?

0 1 2 3 4 5 6 7

8) On average how long did each of these specific exercise sessions last?

_____ mins

Blood Sugar Testing

9) On how many of the last SEVEN DAYS did you test your blood sugar?

0 1 2 3 4 5 6 7

10) On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?

0 1 2 3 4 5 6 7

Foot Care

11) On how many of the last SEVEN DAYS did you check you feet?

0 1 2 3 4 5 6 7

12) On how many of the last SEVEN DAYS did you inspect the inside of your shoes?

0 1 2 3 4 5 6 7

Smoking

13) Have you smoked a cigarette – even one puff – during the last SEVEN DAYS?

0. No

1. Yes *If yes,* how many cigarettes did you smoke on an average day?

Number of cigarettes: _____

The following questions ask you about how likely you would be to change your behaviour if advised to do so by your diabetes team. Please indicate the extent to which you agree or disagree with each statement.

1. I would be prepared to change the amount I test my blood sugars if advised to do so by my diabetes team

Strongly disagree	*Moderately disagree*	*Slightly disagree*	*Neither agree nor disagree*	*Slightly agree*	*Moderately agree*	*Strongly agree*

2. I would be prepared to make changes to my diet if advised to do so by my diabetes team

Strongly disagree	*Moderately disagree*	*Slightly disagree*	*Neither agree nor disagree*	*Slightly agree*	*Moderately agree*	*Strongly agree*

3. I would be prepared to make changes to the amount I exercise if advised to do so by my diabetes team

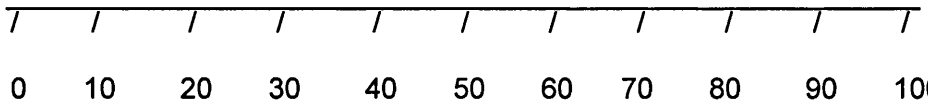
Strongly disagree	*Moderately disagree*	*Slightly disagree*	*Neither agree nor disagree*	*Slightly agree*	*Moderately agree*	*Strongly agree*

4. I would be prepared to make changes to my medication (including changing onto insulin) if advised to do so by my diabetes team

Strongly disagree	*Moderately disagree*	*Slightly disagree*	*Neither agree nor disagree*	*Slightly agree*	*Moderately agree*	*Strongly agree*

Treatment of diabetes involves several self-care activities (e.g. diet, exercise etc.). People sometimes find it difficult to perform one or more of these behaviours. We would like to know how this applies to you. Please circle the number that corresponds best to your situation.

1. How confident are you in your ability to follow your diet?

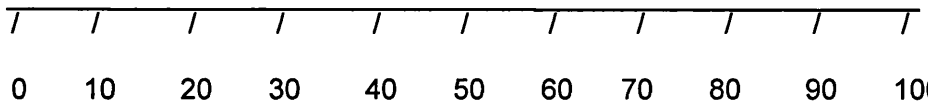


0 10 20 30 40 50 60 70 80 90 100

Not at all confident — Very confident

2. How confident are you in your ability to test your blood sugar at the recommended frequency?

(____ Check here if measuring of blood sugar levels has **not** been recommended)

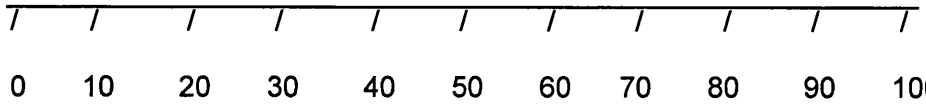


0 10 20 30 40 50 60 70 80 90 100

Not at all confident — Very confident

3. How confident are you in your ability to exercise regularly?

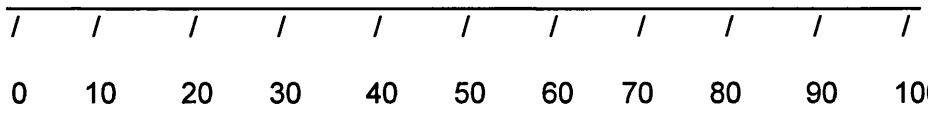
(____ Check here if you have been advised **not** to exercise)



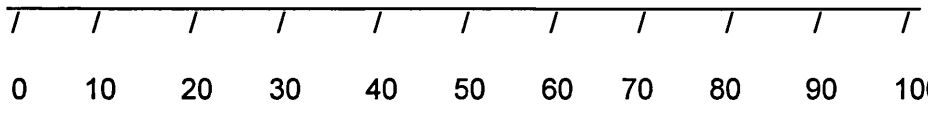
0 10 20 30 40 50 60 70 80 90 100

Not at all confident — Very confident

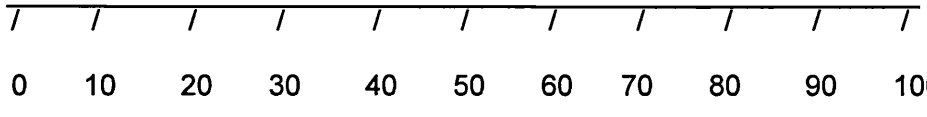
4. How confident are you in your ability to keep your weight under control?



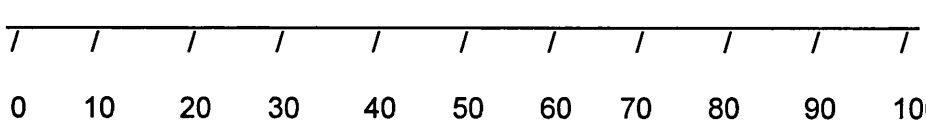
5. How confident are you in your ability to keep your blood sugar level under control?



6. How confident are you in your ability to resist food temptations?



7. How confident are you in your ability to follow your diabetes treatment (diet, medication, blood sugar testing, physical activities)?



Please circle the answer that best describes how you feel about these questions:

1. How serious is your diabetes?

Not at all serious	*Slightly serious*	*Fairly serious*	*Very Serious*	*Extremely serious*

2. How worried are you about developing complications of diabetes (like eye problems, foot ulcers or heart attacks)?

Not at all worried	*Slightly worried*	*Fairly worried*	*Very worried*	*Extremely worried*

3. How important is following your self-care recommendations (for example, diet, exercise and glucose testing) for controlling your diabetes?

Not at all Important	*Slightly important*	*Fairly important*	*Very important*	*Extremely important*

4. How frustrated do you feel when trying to take care of your diabetes?

Not at all frustrated	*Slightly frustrated*	*Fairly frustrated*	*Very frustrated*	*Extremely frustrated*

5. How important is controlling your blood sugar levels for avoiding complications from your diabetes?

Not at all Important	*Slightly important*	*Fairly important*	*Very important*	*Extremely important*

6. How much has having diabetes changed your activities (that is your family and social events, work, and hobbies)?

Not at all	*Slightly*	*Moderately*	*A lot*	*Completely*

7. How important do you believe healthy eating is for controlling your diabetes?

Not at all Important	*Slightly important*	*Fairly important*	*Very important*	*Extremely important*

8. How likely do you think it is that healthy eating will prevent future complications of your diabetes?

Not at all Likely	*Slightly likely*	*Fairly likely*	*Very likely*	*Extremely likely*

9. How important do you believe physical activity is for controlling your diabetes?

Not at all Important	*Slightly important*	*Fairly important*	*Very important*	*Extremely important*

10. How likely do you think it is that physical activity will prevent future complications of your diabetes?

Not at all Likely	*Slightly likely*	*Fairly likely*	*Very likely*	*Extremely likely*

11. How much control do you feel you have over your blood sugar levels?

None	*Slightly*	*Moderately*	*A lot*	*Completely*

We want to know how often family members or close friends do several things related to your daily self-care activities Rate the family member or close friend with whom you generally have the most contact. Just put down what happens usually– there are no right or wrong answers.

Family member or friend you are rating (circle one)
1. husband 2. Wife 3. Partner 4. Sibling 5. Child 6. Friend 7. Other _____

How much time do you spend with this person on a typical day? (count only waking hours) _____ hours

How much does this person know about diabetes? Please circle a number below

Hardly Anything — Moderate amount — A great deal
1 2 3 4 5 6 7

	Never	Once a month	Once a week	Several times a week	At least once a day
Praise you for following your diet	1	2	3	4	5
Nag you about testing your blood sugar level	1	2	3	4	5
Suggest things that might help you take your diabetes medication on time	1	2	3	4	5
Criticise you for not exercising regularly	1	2	3	4	5
Help you decide if changes should be made based on blood sugar readings	1	2	3	4	5
Nag you about following your diet	1	2	3	4	5
Argue with you about your diabetes self-care activities	1	2	3	4	5
Encourage you to participate in sports activities	1	2	3	4	5
Plan family activities so that they will fit in with your diabetes self-care schedule	1	2	3	4	5

	Never	Once a month	Once a week	Several times a week	At least once a day
Congratulate you for sticking to your diabetes self-care schedule	1	2	3	4	5
Eat at the same time that you do	1	2	3	4	5
Exercise with you	1	2	3	4	5
Let you sleep late rather than getting up to take your diabetes medication	1	2	3	4	5
Buy you things containing sugar to carry with you in case of a hypoglycaemic reaction	1	2	3	4	5
Eat foods that are not part of your diabetic diet	1	2	3	4	5

Other supportive or non-supportive things he/she does _____

The following questions relate to both family and friends. Please indicate the extent to which you agree or disagree with each statement.

	Strongly disagree	Moderately disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Moderately agree	Strongly agree
There is a special person who is around when I am in need	1	2	3	4	5	6	7
There is a special person with whom I can share my joys and sorrows	1	2	3	4	5	6	7
My family really tries to help me	1	2	3	4	5	6	7
I get the emotional help and support I need from my family	1	2	3	4	5	6	7
I have a special person who is a real source of comfort to me	1	2	3	4	5	6	7
My friends really try to help me	1	2	3	4	5	6	7
I can count on my friends when things go wrong	1	2	3	4	5	6	7
I can talk about my problems with my family	1	2	3	4	5	6	7
There is a special person in my life who cares about my feelings	1	2	3	4	5	6	7
My family is willing to help me make decisions	1	2	3	4	5	6	7
I can talk about my problems with my friends	1	2	3	4	5	6	7
I have friends with whom I can share my joys and sorrows	1	2	3	4	5	6	7

The following scale consists of a number of words that describe different feelings and emotions. Read each item and then mark the appropriate answer in the space next to that word. Indicate to what extent you have felt this way **during the past week**.

	Very slightly or not at all	A little	Moderately	Quite a bit	Extremely
Distressed	1	2	3	4	5
Excited	1	2	3	4	5
Upset	1	2	3	4	5
Scared	1	2	3	4	5
Enthusiastic	1	2	3	4	5
Alert	1	2	3	4	5
Inspired	1	2	3	4	5
Nervous	1	2	3	4	5
Determined	1	2	3	4	5
Afraid	1	2	3	4	5

No: _____ Date: _____

Has a doctor ever told you that you have been diagnosed with any of the following. If so please tell us how much it currently affects your life. (circle one answer)

Diagnosed?		**If yes, how much does it affect your life**			
Diabetes	Yes /No	Not at all	A little	A lot	A great deal
Stroke	Yes /No	Not at all	A little	A lot	A great deal
Asthma	Yes /No	Not at all	A little	A lot	A great deal
Heart Disease	Yes /No	Not at all	A little	A lot	A great deal
Arthritis	Yes /No	Not at all	A little	A lot	A great deal
Cancer	Yes /No	Not at all	A little	A lot	A great deal
High Blood Pressure	Yes /No	Not at all	A little	A lot	A great deal
Eye Disease	Yes /No	Not at all	A little	A lot	A great deal
Kidney Disease	Yes /No	Not at all	A little	A lot	A great deal
Peripheral Neuropathy	Yes /No	Not at all	A little	A lot	A great deal
Microalbuminuria	Yes/No	Not at all	A little	A lot	A great deal
Other		Not at all	A little	A lot	A great deal
Other		Not at all	A little	A lot	A great deal

Now, please list the conditions you have been diagnosed with in the order in which they affect your life. Begin with the one that affects you the most.

1. _____ 4. _____

2. _____ 5. _____

3. _____ 6._____

No: _____ Date: _____

The following questions ask you about your health in general and are not just specific to diabetes. Please remember that there are no right or wrong answers and you should give the answer that best reflects how you feel.

Your Health

1. In general, would you say your health is:

(Circle One Number)

Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. **Compared to one year ago**, how would you rate your health in general **now**?

(Circle One Number)

Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same as one year ago	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

3. During the **past 4 weeks**, did you work at a paying job?

(Circle One Number)

Yes	1
No	2

4. Does your health keep you from working at a paying job?

(Circle One Number)

Yes	1
No	2

No: _____ Date: _____

5. The following items are about activities you might do during a typical day. **Does your health now limit** you in these activities? If so, how much?

(Circle One Number on Each Line)

	Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
a. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying shopping bags	1	2	3
d. Climbing **several** flights of stairs	1	2	3
e. Climbing **one** flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking **more than a mile**	1	2	3
h. Walking **half a mile**	1	2	3
i. Walking **100 yards**	1	2	3
j. Bathing or dressing yourself	1	2	3

6. Please choose the answer that best describes how **TRUE** or **FALSE** each of the following statements is for you.

(Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get ill more easily than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

No: _____ Date: _____

7. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(Circle One Number on Each Line)

	Yes	No
a. Cut down the **amount of time** you spent on work or other activities?	1	2
b. **Accomplished less** than you would have liked?	1	2
c. Were limited in the **kind** of work or other activities?	1	2
d. Had **difficulty** performing the work or other activities (for example, it took extra effort)?	1	2

8. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(Circle One Number on Each Line)

	Yes	No
a) Cut down the **amount of time** you spent on work or other activities?	1	2
b) **Accomplished less** than you would have liked?	1	2
c) Didn't do work or other activities **as carefully as usual**?	1	2

9. During the **past 4 weeks**, to what **extent** have your **physical health or emotional problems** interfered with your normal social activities with family, friends, neighbours, or clubs?

(Circle One Number)

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

No: _____ Date: _____

10. How much **bodily** pain have you had during the **past 4 weeks**?

(Circle One Number)

None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6

11. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

(Circle One Number)

Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

No: _____ Date: _____

12. These questions are about how you feel and how things have been with you during the **past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

    How much of the time during the **past 4 weeks...**

		(Circle One Number on Each Line)					
		All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a.	Did you feel full of life?	1	2	3	4	5	6
b.	Have you been a very nervous person?	1	2	3	4	5	6
c.	Have you felt so down in the dumps that nothing could cheer you up?.....	1	2	3	4	5	6
d.	Have you felt calm and peaceful?	1	2	3	4	5	6
e.	Did you have a lot of energy?.	1	2	3	4	5	6
f.	Have you felt downhearted and unhappy?.....	1	2	3	4	5	6
g.	Did you feel worn out?	1	2	3	4	5	6
h.	Have you been a happy person?.....	1	2	3	4	5	6
i.	Did you feel tired?	1	2	3	4	5	6
j.	How much of your time has your health or emotional problems limited your social activities	1	2	3	4	5	6

No: _____ Date: _____

The following questions are designed to help us know how you feel. Please answer each question by circling one answer.

1. I feel tense or wound up

Most of the time	1
A lot of the time	2
From time to time, occasionally	3
Not at all	4

2. I still enjoy the things I used to enjoy

Definitely as much	1
Not quite as much	2
Only a little	3
Hardly at all	4

3. I get a sort of frightened feeling as if something awful is about to happen:

Very definitely and quite badly	1
Yes, but not too badly	2
A little, but it doesn't worry me	3
Not at all	4

4. I can laugh and see the funny side of things:

As much as I always could	1
Not quite so much now	2
Definitely not so much now	3
Not at all	4

No: _____ Date: _____

5. Worrying thoughts go through my mind

A great deal of the time	1
A lot of the time	2
From time to time but not too often	3
Only occasionally	4

6. I feel cheerful

Not at all	1
Not often	2
Sometimes	3
Most of the time	4

7. I can sit at ease and feel relaxed

Definitely	1
Usually	2
Not often	3
Not at all	4

8. I feel as if I am slowed down

Nearly all the time	1
Very often	2
Sometimes	3
Not at all	4

No: _____ Date: _____

9. I get a sort of frightened feeling like 'butterflies' in the stomach:

Not at all	1
Occasionally	2
Quite often	3
Very often	4

10. I have lost interest in my appearance:

Definitely	1
I don't take as much care as I should	2
I may not take quite as much care	3
I take just as much care as ever	4

11. I feel restless as if I have to be on the move:

Very much indeed	1
Quite a lot	2
Not very much	3
Not at all	4

12. I look forward with enjoyment to things:

As much as ever I did	1
Rather less than I used to	2
Definitely less than I used to	3
Hardly at all	4

No: _____ Date: _____

13. I get sudden feelings of panic

Very often indeed	1
Quite often	2
Not very often	3
Not at all	4

14. I can enjoy a good book or radio or TV programme:

Often	1
Sometimes	2
Not often	3
Very seldom	4

No: _____ Date: _____

Please indicate the medication you take for your diabetes

Name	Frequency	Dose

Please indicate the medication you take for any other conditions

Name	Frequency	Dose

Thank you for completing this questionnaire

APPENDIX THREE

COMPARISON OF PARTICIPANTS AND NON-PARTICIPANTS

The table A3.1 shows a comparison of study participants and non-participants on basic demographic and clinical variables. No differences were seen between the groups on any of these variables.

Table A3.1

	Participants	**Non-Participants**	**Statistical Significance**
Gender (% Male)	70.9	65.8	χ^2 (,df =1), p=0.41
Age (yrs) (mean ± s.d.)	59.85 (8.75)	62.39(9.87)	t (-1.79, df =187), p=0.08
Years Diagnosed (mean ± s.d.)	10.76 (7.58)	10.09(6.35)	t (0.59, df=185), p=0.56

APPENDIX FOUR

NORMALITY TESTS ON BASELINE DATA

Appendix 4: Normality Tests on Baseline Subscales

Measure (including sub-scales)	Kolmogorov Smirnov Z	Statistical Significance
HbA1c (n=123)	1.089	0.187
Systolic Blood Pressure (n=92)	0.684	0.738
Diastolic Blood Pressure (n=91)	0.819	0.513
SDSCA Scale (n=124)		
General Diet*	1.842	0.002
Specific Diet†	1.147	0.144
Exercise*	1.641	0.009
SMBG*	2.301	0.000
Foot-Care	1.977	0.001
ADDQoL (n=124)*		
Item A	2.029	0.001
Item B	2.963	0.00
Total	1.091	0.185
SF-36 (n=122)		
Physical Functioning	1.642	0.009
Role Physical	3.019	0.000
Role Emotional	4.919	0.000
Social Functioning	2.585	0.000
Mental Health	1.348	0.604
Energy/Vitality	0.764	0.001
Pain	1.914	0.053
General Health	0.765	0.602
Physical Composite Scale*	1.238	0.093
Mental Composite Scale*	1.066	0.206
HAD Scale (n=116)		
Depression*	1.948	0.001
Anxiety*	1.284	0.245

Measure (including sub-scales)	Kolmogorov Smirnov Z	Statistical Significance
PANAS(n=114)		
Negative Affect*	1.926	0.001
Positive Affect*	1.025	0.245
MDRTC Knowledge (n=119)*	1.087	0.188
Self-Efficacy Scale (n=119)*		
Total	0.872	0.432
Diet	1.831	0.002
SMBG	2.542	0.000
Exercise	1.255	0.086
RTC (n=108)		
Diet	3.332	0.000
Exercise	3.229	0.000
SMBG	2.338	0.000
Medication	3.490	0.000
Personal Models of Diabetes (n=124)		
Seriousness*	1.653	0.008
Treatment Effectiveness*	1.101	0.177
Control†	2.569	0.000
DFBC-II (n=95)		
Diet	1.101	0.177
Exercise	1.709	0.006
SMBG	2.991	0.000
Medication	3.375	0.000
Positive Support	1.362	0.049
Negative Support	1.052	0.218
MSPss (n=112)		
Significant Other*	2.607	0.000
Family*	2.178	0.000
Friend*	1.321	0.061
Total*	1.895	0.002

APPENDIX FIVE

CORRELATION ANALYSIS OF BASELINE DATA

Appendix 5: Correlation Analysis of Baseline Variables

	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.
1. Age	1.000										
N	124										
2. Years diagnosed	.255**	1.000									
N	122	122									
3. Diabetes complications	.241**	.139	1.000								
N	124	122	124								
4. BP – diastolic	-.061	.080	-.030	1.000							
N	91	90	91	91							
5. BP – systolic	.203	.352***	.048	.597***	1.000						
N	92	91	92	91	92						
6. HbA1c	-.168	.119	.090	.108	.053	1.000					
N	123	121	123	91	92	123					
7. General diet	.063	.170	-.127	-.048	.083	.079	1.000				
N	124	122	124	91	92	123	124				
8. Fruit	-.193*	-.103	-.180*	.030	.014	.105	.304***	1.000			
N	124	122	124	91	92	123	124	124			
9. Fat	.082	-.045	-.002	.091	.062	-.078	.189*	-.47	1.000		
N	124	122	124	91	92	123	124	124	124		
10. Exercise	-.160	.015	-.207*	.112	.054	-.005	.228*	.289***	-.091	1.000	
N	124	122	124	91	92	123	124	124	124	124	
11. SMBG	.000	.175	.030	-.084	.014	.171	.204*	.096	.020	-.125	1.000
N	124	122	124	91	92	123	124	124	124	124	124
12. ADDQoL item a	-.080	.011	.031	.079	-.075	.013	-.140	.107	-.075	.102	-.047
N	123	121	123	90	91	122	123	123	123	123	123
13. ADDQoL item b	-.188*	-.194*	-.180	.073	-.065	-.159	-.117	.129	.042	-.017	-.138
N	111	109	111	84	85	110	111	111	111	111	111
14. ADDQoL weighted total	-.016	-.106	-.260**	.112	.147	-.134	-.016	.082	.024	-.071	-.071
N	124	122	124	91	92	123	124	124	124	124	124
15. SF-36 physical functioning	-.161	-.170	-.333***	.132	.095	-.045	.156	.245**	.147	.230*	-.129
N	122	120	122	90	91	121	122	122	122	122	122
16. SF-36 social functioning	-.054	-.035	-.093	.228*	.282**	-.126	-.011	.102	.114	.155	-.247**
N	122	120	122	90	91	121	122	122	122	122	122

	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.
17.SF-36 role emotional	.028	-.132	-.204*	.150	.194	-.052	-.062	.021	.137	.083	-.244**
N	122	120	122	90	91	121	122	122	122	122	122
18.SF-36 role physical	-.073	-.150	-.262**	.169	.174	-.024	-.013	.184*	.128	.108	-.227*
N	122	120	122	90	91	121	122	122	122	122	122
19.SF-36 energy vitality	-.054	-.119	-.144	.239*	.106	-.099	.146	.155	.224*	.222*	-.162
N	122	120	122	90	91	121	122	122	122	122	122
20.SF-36 general	.029	-.209*	-.287***	.168	.162	-.139	.098	.177	.243**	.148	-.231*
health perception N	122	120	122	90	91	121	122	122	122	122	122
21.SF-36 mental health	.073	-.041	.021	.065	.199	.020	.199*	.151	.171	.179*	-.073
N	122	120	122	90	91	121	122	122	122	122	122
22.SF-36 pain time 1	.128	-.081	-.102	.144	.217*	-.035	.064	.010	.232**	.088	-.207*
N	122	120	122	90	91	121	122	122	122	122	122
23.SF-36 physical	-.059	-.170	-.302***	.186	.178	-.070	.084	.190*	.200*	.168	-.223*
composite N	122	120	122	90	91	121	122	122	122	122	122
24.SF-36 mental	.054	-.063	-.031	.179	.228*	-.073	.050	.066	.170	.153	-.195*
composite N	122	120	122	90	91	121	122	122	122	122	122
25. Anxiety	-.068	-.123	.065	-.214*	-.401***	-.002	-.188*	-.021	-.150	-.007	.035
N	116	114	116	85	86	115	116	116	116	116	116
26. Depression	-.018	-.054	.103	-.056	-.153	.174	-.231*	-.145	-.038	-.095	-.009
N	116	114	116	85	86	115	116	116	116	116	116
27. Negative affect	-.147	.000	.108	-.173	-.259*	.097	.047	.047	-.160	.094	.134
N	114	112	114	85	86	113	114	114	114	114	114
28. Positive affect	-.236*	-.010	.021	-.046	-.025	-.001	-.015	.255**	-.084	.283**	-.114
N	114	112	114	85	86	113	114	144	114	114	114
29. Self-efficacy diet	.050	.250**	-.128	.101	.115	-.013	.644***	.248**	.216*	.220*	.111
N	121	119	121	89	90	120	121	121	121	121	121
30. Self-efficacy SMBG	-.063	.163	-.024	-.100	-.081	-.146	.023	-.071	.011	-.015	.384***
N	102	100	102	73	73	101	102	102	102	102	102
31. Self-efficacy	.012	.035	.007	.001	.010	.018	.335***	.165	.088	.566***	.023
exercise N	120	118	120	89	90	119	120	120	120	120	120
32. Self-efficacy total	.130	.167	-.069	.030	.038	-.058	.569***	.222*	.242**	.300***	.161
N	119	117	119	88	89	118	119	119	119	119	119
33. RTC - SMBG	-.051	.046	.116	-.189	-.153	.010	.154	-.028	.028	-.024	.266***
N	120	118	120	88	89	119	120	120	120	120	120

	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.
34. RTC - Diet	.045	.020	.033	-.017	-.092	-.011	.173	.096	.113	.128	.121
N	120	118	120	88	89	119	120	120	120	120	120
35. RTC – Exercise	-.018	.040	.017	.024	-.098	.069	.155	.063	.189*	.246***	.149
N	120	118	120	88	89	119	120	120	120	120	120
36. RTC – medication	-.023	.209	.024	-.025	.029	.026	.192	.093	-.053	.078	.223*
N	120	118	120	88	89	119	120	120	120	120	120
37. Belief in seriousness	-.089	.211*	.139	.043	.040	.193*	.125	.123	-.116	.042	.249**
N	124	122	124	91	92	123	124	124	124	124	124
38. Belief in treatment effectiveness	-.232**	-.040	-.003	-.077	-.165	.008	.157	.318***	.015	.225*	.245**
N	124	122	124	91	92	123	124	124	124	124	124
39. Belief in control	-.008	.019	-.036	.083	.068	-.170	.267**	.109	.107	.151	.023
N	124	122	124	91	92	123	124	124	124	124	124
40. Knowledge	-.417***	-.012	.021	-.115	-.099	.143	-.062	.245**	-.179	.102	.141
N	119	117	119	89	90	118	119	119	119	119	119
41. Social support family	.130	.164	.097	-.199	-.146	-.041	.112	.030	.031	-.013	.113
N	112	110	112	83	84	111	112	112	112	112	112
42. Social support friends	-.054	.035	.016	-.117	-.097	.088	.217*	.137	.112	.160	.137
N	112	110	112	83	84	111	112	112	112	112	112
43. Social support significant others	.143	.213*	.079	-.117	-.010	-.092	.234*	.165	.112	.064	.021
N	112	110	112	83	84	111	112	112	112	112	112
44. Social support total	.098	.172	.081	-.176	-.102	-.026	.222*	.129	.099	.077	.107
N	112	110	112	83	84	111	112	112	112	112	112

	12	13	14	15	16	17	18	19	20	21	22
12. ADDQoL item a	1.000										
N	123										
13. ADDQoL item b	-.008	1.000									
N	110	111									
14. ADDQoL weighted total	-.051	.603***	1.000								
N	123	111	124								
15.SF-36 physical functioning	.054	.376***	.399***	1.000							
N	121	110	122	122							
16.SF-36 social functioning	-.026	.380***	.465***	.545***	1.000						
N	121	110	122	122	122						
17.SF-36 role emotional	-.021	.274**	.405***	.431***	.629***	1.000					
N	121	110	122	122	122	122					
18. SF-36 role physical	-.023	.365***	.276**	.639***	.583***	.588***	1.000				
N	121	110	122	122	122	122	122				
19. SF-36 energy vitality	-.019	.199*	.225*	.646***	.545***	.385***	.552***	1.000			
N	121	110	122	122	122	122	122	122			
20.SF-36 general health perception	-.020	.314***	.331***	.551***	.570***	.387***	.604***	.627***	1.000		
N	121	110	122	122	122	122	122	122	122		
21.SF-36 mental health	-.018	.218*	.239**	.395***	.498***	.474***	.334***	.447***	.322***	1.000	
N	121	110	122	122	122	122	122	122	122	122	
22. SF-36 pain	-.149	.029	.176	.539***	.473***	.533***	.528***	.485***	.428***	.408***	1.000
N	121	110	122	122	122	122	122	122	122	122	122
23. SF-36 physical composite	-.040	.314***	.330***	.865***	.622***	.478***	.834***	.675***	.729***	.318***	.755***
N	121	110	122	122	122	122	122	122	122	122	122
24. SF-36 mental composite	-.021	.267**	.359***	.315***	.733***	.780***	.422***	.588***	.453***	.783***	.371***
N	121	110	122	122	122	122	122	122	122	122	122
25. Anxiety	.037	-.128	-.297***	-.318***	-.458***	-.372***	-.336***	-.378***	-.313***	-.634***	-.426***
N	115	103	116	115	115	115	115	115	115	115	115
26. Depression	-.013	-.246*	-.344***	-.492***	-.519***	-.408***	-.393***	-.452***	-.469***	-.555***	-.330***
N	115	103	116	115	115	115	115	115	115	115	115
27. Negative affect	.120	-.061	-.265**	-.201*	-.515***	-.557***	-.327***	-.402***	-.398***	-.522***	-.441***
N	113	102	114	114	114	114	114	114	114	114	114

	12	13	14	15	16	17	18	19	20	21	22
28. Positive affect	.248**	.092	-.036	.125	.001	-.088	.041	.034	.009	-.101	-.146
N	113	102	114	114	114	114	114	114	114	114	114
29. Self-efficacy diet	-.085	-.115	-.127	.213*	-.067	-.188*	-.035	.223*	.104	.077	.048
N	120	108	121	120	120	120	120	120	120	120	120
30. Self-efficacy SMBG	.049	.099	-.003	-.040	-.021	-.142	-.111	-.038	-.054	.072	-.068
N	101	91	102	101	101	101	101	101	101	101	101
31. Self-efficacy exercise	-.021	-.329***	-.159	.225*	.119	-.053	-.013	.341***	.134	.122	.136
N	119	107	120	119	119	119	119	119	119	119	119
32. Self-efficacy total	-.048	-.135	-.114	.290***	.079	-.097	.037	.369***	.224	.177*	.166
N	118	106	119	118	118	118	118	118	118	118	118
33. RTC - SMBG	-.152	.096	-.039	-.077	-.035	-.133	-.118	-.086	-.030	-.075	-.034
N	119	107	120	119	119	119	119	119	119	119	119
34. RTC - Diet	-.030	-.004	-.073	.011	-.104	-.062	.028	.036	.019	.012	-.018
N	119	107	120	119	119	119	119	119	119	119	119
35. RTC – Exercise	.053	-.077	-.086	.106	.020	-.093	.040	.287**	.183*	.001	.005
N	119	107	120	119	119	119	119	119	119	119	119
36. RTC – medication	-.073	.125	.137	.091	.179	.030	.144	.010	.021	.109	.039
N	119	107	120	119	119	119	119	119	119	119	119
37. Belief in seriousness	.084	-.410***	-.526***	-.295***	-.454***	-.411***	-.344***	-.262**	-.358***	-.342*	-.251**
N	123	111	124	122	122	122	122	122	122	122	122
38. Belief in treatment effectiveness	.156	-.069	-.148	.140	-.024	-.090	-.076	.073	.030	-.052	-.056
N	123	111	124	122	122	122	122	122	122	122	122
39. Belief in control	.061	.015	-.009	.329***	.081	.049	.154	.277**	.182*	-.001	.207*
N	123	111	124	122	122	122	122	122	122	122	122
40. Knowledge	.157	-.061	.020	.047	-.046	-.153	-.038	-.114	-.198*	-.180	-.164
N	118	106	119	118	118	118	118	118	118	118	118
41. Social support family	.028	-.052	-.172	.077	-.058	-.134	-.001	-.010	-.071	.007	-.046
N	111	101	112	110	110	110	110	110	110	110	110
42. Social support friends	-.006	.030	-.105	.144	-.112	-.114	.010	.015	.097	.103	-.060
N	111	101	112	110	110	110	110	110	110	110	110
43. Social support significant others	.026	.059	-.064	.185	.111	-.020	.079	.112	.024	.183	-.014
N	111	101	112	110	110	110	110	110	110	110	110
44. Social support total	.021	.012	-.140	.162	-.019	-.109	.036	.047	.012	.115	-.048
N	111	101	112	110	110	110	110	110	110	110	110

	23.	24.	25.	26.	27.	28.	29.	30.	31.	32.	33.
23.SF-36 physical composite	1.000										
N	122										
24.SF-36 mental composite	.322***	1.000									
N	122	122									
25. Anxiety	-.355***	-.545***	1.000								
N	115	115	116								
26. Depression	-.451***	-.535***	.595***	1.000							
N	115	115	116	116							
27. Negative affect	-.313***	-.661***	.576***	.377***	1.000						
N	114	114	110	110	114						
28. Positive affect	.041	-.099	.296	-.064	.272**	1.000					
N	114	114	110	110	114	114					
29. Self-efficacy diet	.126	-.073	-.207*	-.233*	.068	-.019	1.000				
N	120	120	115	115	114	114	121				
30. Self-efficacy SMBG	-.078	-.030	-.130	-.052	-.005	-.063	.217*	1.000			
N	101	101	96	96	96	96	102	102			
31. Self-efficacy exercise	.161	.095	-.083	-.156	.052	.164	.478***	.048	1.000		
N	119	119	114	114	114	114	120	102	120		
32. Self-efficacy total	.231*	.065	-.226*	-.313***	-.014	-.059	.811***	.410***	.652***	1.000	
N	118	118	114	114	113	113	119	101	119	119	
33. RTC - SMBG	-.062	-.103	.151	.016	.099	-.020	.028	.245*	-.066	.065	1.000
N	119	119	114	114	113	113	120	102	119	118	120

34. RTC - Diet	.012	-.049	.070	-.066	.124	.102	.235**	.020	.179	.263**	.317***
N	119	119	114	114	113	113	120	102	119	118	120
35. RTC – Exercise	.108	.028	.057	-.046	-.007	.179	.188*	-.029	.412***	.261**	.155
N	119	119	114	114	113	113	120	102	119	118	120
36. RTC – medication	.101	.064	-.136	-.231*	-.002	-.058	.095	.099	.028	.164	.379***
N	119	119	114	114	113	113	120	102	119	118	120
37. Belief in seriousness	-.327***	-.431***	.329***	.361***	.298***	.126	.193*	-.085	.052	.087	.049
N	122	122	116	116	114	114	121	102	120	119	120
38. Belief in treatment effectiveness	.036	-.076	.222*	.090	.181	.237*	.123	.187	.195*	.190*	.228*
N	122	122	116	116	114	114	121	102	120	119	120

	23.	24.	25.	26.	27.	28.	29.	30.	31.	32.	33.
39. Belief in control	.300***	-.009	-.070	-.170	.045	.055	.284**	.121	.132	.383***	.088
N	122	122	116	116	114	114	121	102	120	119	120
40. Knowledge	-.045	-.210*	.187*	.087	.217*	.375***	-.147	.041	-.029	-.176	.056
N	118	118	113	113	113	113	118	100	118	117	117
41. Social support	.017	-.111	-.047	-.224*	.166	-.087	.127	-.075	.114	.179	.115
family N	110	110	107	107	107	107	111	93	110	109	111
42. Social support	.056	-.074	-.012	-.317***	.081	.132	.168	.004	.085	.200*	.217*
friends N	110	110	107	107	107	107	111	93	110	109	111
43. Social support	.089	.078	-.153	-.296**	.034	.071	.262**	-.005	.145	.278**	.020
significant others N	110	110	107	107	107	107	111	93	110	109	111
44. Social support total	.064	-.044	-.087	-.333***	.117	.035	.223*	-.033	.140	.263**	.134
N	110	110	107	107	107	107	111	93	110	109	111

	34.	35.	36.	37.	38.	39.	40.	41.	42.	43.	44.
35. RTC – Exercise	.554***	1.000									
N	120	120									
36. RTC – medication	.300***	.203*	1.000								
N	120	120	120								
37. Belief in serious.	.130	.058	-.026	1.000							
N	120	120	120	124							
38. Belief in treat Eff.	.201*	.165	.090	.343***	1.000						
N	120	120	120	124	124						
39. Belief in control	.111	.043	-.011	.164	.348***	1.000					
N	120	120	120	124	124	124					
40. Knowledge	-.128	-.118	.052	.207*	.343***	.031	1.000				
N	117	117	117	119	119	119	119				
41. Social sup family	.349***	.230*	.192*	.058	.052	.049	-.038	1.000			
N	111	111	111	112	112	112	109	112			
42. Social sup friends	.340***	.211*	.121	.076	.202*	.146	.082	.377***	1.000		
N	111	111	111	112	112	112	109	112	112		
43. Social sup	.305***	.146	.065	-.096	.060	.127	-.042	.679***	.487***	1.000	
significant others N	111	111	111	112	112	112	109	112	112	112	
44. Social support total	.399***	.235*	.154	.013	.118	.125	-.006	.858***	.718***	.887***	1.000
N	111	111	111	112	112	112	109	112	112	112	112

APPENDIX SIX

PUBLICATIONS FROM THE STUDY

The Development and Evaluation of the UCL- Diabetes Self-Management Programme (UCL-DSMP)

Submitted by Elizabeth Steed
For the degree of PhD at University College London

Volume Two

The UCL-Diabetes Self-Management Programme (UCL-DSMP)

Facilitator's Manual

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CONTENTS

INTRODUCTION

Type 2 diabetes has sometimes been thought of as a milder or less serious form of diabetes than type 1 diabetes. This is not the case and type 2 diabetes is associated with much the same complications and reduction of quality of life as type 1 diabetes. To reduce these complications tight control of blood sugars and blood pressure is paramount.

Good control in diabetes can however be a challenge for the patient who is required to follow a complex and ongoing behavioural regimen. Typically, this will entail following dietary and exercise plans, taking medication, giving up smoking, and frequent monitoring of blood sugars. Patients often find it difficult to make the necessary behavioural changes to follow this regimen with the consequence that blood sugar control is often less than ideal.

The aim of this programme is to target the necessary behaviour changes important in type 2 diabetes. It will teach patients how they can successfully make and maintain these changes even in the face of difficulties. By helping individuals make these behaviour changes it is hoped that blood sugar and blood pressure levels will improve, with a long-term aim of decreasing complications.

What Does the Programme Entail?

The programme takes place over five weeks with one 2.5 hour session per week. In addition one booster session is held after three months. All sessions are ideally run jointly by a diabetes specialist nurse and a dietician. However, it is possible to have one principal group leader (e.g. primary care nurse) with specialised input from a diabetes specialist nurse and dietician as appropriate.

The style of the programme is such that much of the learning will occur from within the group. The programme is not designed to be didactic and to this end the group leader and specialist nurse and dieticians should act as facilitators rather than solely educators.

The five key topics explored within the programme are:

1. What is Diabetes and Why is Self-Management Important?
2. Home Blood Glucose Monitoring (HBGM)
3. Healthy Eating and Diabetes
4. Exercise and Diabetes
5. Medication and Diabetes

The first topic serves to introduce the concept of self-management and provides an understanding of why tight blood sugar and blood pressure control is important.

The subsequent four topics are all areas which may require behaviour change. In addressing these topics four main components are applied:

1. Knowledge
2. Practical skills
3. Problem solving techniques to overcome barriers
4. Patient beliefs

Previous self-management programmes have typically only concentrated on the first two of these components. While knowledge and practical skills are necessary for self-management they are often not sufficient for behaviour change. Take for example the individual who knows that exercise is beneficial and is physically capable of an active lifestyle but still remains sedentary.

To obtain behaviour change one must consider what barriers i.e. what factors it is that stands in the way of behaviour change. Barriers can be either practical or psychological and can be tackled by teaching problem solving skills. Among the techniques taught are teaching individuals to break down barriers into manageable chunks and then identify strategies to deal with each problem in turn. Behavioural strategies of goal setting and self-reinforcement are also used to assist the problem solving process.

Psychological barriers may be even more difficult to overcome than practical barriers and require consideration of an individuals belief system in relation to diabetes. Throughout the programme unhelpful or negative beliefs are challenged where appropriate. However, four beliefs are seen as central to behaviour change in diabetes and are therefore specifically addressed by the programme. In the first session two general beliefs which are seen as fundamental to self-management are addressed. These are:

- That diabetes is a serious condition that is worthy of appropriate care
- That the participants have an important role to play in the care of their diabetes

Two more specific beliefs will be addressed in each of the four subsequent sessions. These are:

- That performing the said behaviour as required will have beneficial outcomes for controlling diabetes.
- That the individual has the ability to perform the behaviour as required. An individuals' belief in their ability is known as self-efficacy and will be targeted for each behaviour.

By addressing problem solving and belief systems in addition to knowledge and practical skills, the diabetes self-management programme aims to empower patients with the ability to change and maintain appropriate self-management behaviours.

Programme Overview

Session One	What is Diabetes? What is Self-Management?	*Coffee Break*	Home Blood Glucose Monitoring (HBGM) Goal setting for HBGM
Session Two	HBGM - barriers Food and Diabetes	*Coffee Break*	Healthy Eating Principles and Strategies Goal Setting for Health Eating
Session Three	Healthy Eating - barriers Eating in Social Situations	*Coffee Break*	Benefits of Exercise Barriers to Exercise
Session Four	How to Exercise Safely Goal Setting for Exercise	*Coffee Break*	Medication and Diabetes Sick Days and Medication
Session Five	Barriers to Medication Difficult Situations	*Coffee Break*	Summary of Problem-Solving Maintaining Goals

HOW TO USE THE MANUAL

The manual is designed to be used by the facilitators of the programme and will not be distributed to participants. All programme facilitators must have undertaken the related training programme before running the programme.

The manual is in two sections.

Technique Guides

Throughout the programme a number of techniques will be used such as problem solving, goal-setting, challenging beliefs etc. These techniques will be taught in the training session and reading material distributed. Within the manual summary sheets are provided for each technique. These provide a quick reference guide of how to apply a technique and highlight the main points to convey to the group.

Session Guides

Session guides are written as five individual chapters and are formatted in a consistent way for easy reference. Explanation of the formatting used is provided below:

Manual Headings	
Objectives:	Each session begins with a list of objectives that should be achieved within the session.
Subheadings:	These denote main topics within the session. An approximate time to be spent on each sub-heading is given. An effort should be made to stick to the timings to prevent over-running of the session.
Aims:	Beneath each sub-heading an aim is provided. This summarises the key points to be achieved in that part of the session.
Grey Boxes:	Instructions to the facilitator are provided within the grey boxes. These mainly refer to ordering of the session and provide reminders to the facilitator. In addition examples of how to raise issues are sometimes provided.
Question Probe	These headings are written in bold print and indicate when a question or brainstorming session should be held. Probes are provided which can be used to help the group explore the topic more fully. It may not be necessary to use all the probes if a full discussion is taking place.

Summarise Information	These headings are used to indicate that the information which follows should be discussed with the group. If the heading summarise is used then it is expected that the information will have mainly been drawn from brainstorming with the group. The facilitator's role here is to guide and summarise the discussion and to add any information which may have not been covered in the discussion. Where the heading information is used then it is expected that the facilitator will need to provide the information following a more traditional teaching model. This is used rarely during the programme.
Overhead	This indicates that the facilitator should show an overhead. A copy of the overheads to be used are shown at the end of each session.
Exercise	This indicates that a practical exercise is to be completed. Full details of the exercise are provided at the end of each session.

The purpose of the manual is to ensure a consistency across groups. Sufficient detail is provided to allow this, however, a facilitator should feel free to use his/her own language when conveying information or explaining a concept.

PROBLEM SOLVING/OVERCOMING BARRIERS

Materials Needed

Technique sheets for: Challenging Beliefs
Brainstorming
Goal Setting

Overcoming those problems which act as barriers to self-management, is one of the central aims of the programme. Problem solving skills are taught within the context of each of the four main behaviours addressed in the programme. However, these skills can be generalised to any problem, and this should be emphasised to participants.

The six main steps in problem solving are:

Step One Identification of a Problem

- Most people do not perform self-management behaviours at an optimum level
- Identification of a problem means identifying that the self-management behaviour can be improved.
- If someone is satisfied with their behaviour explore whether they do the behaviour in all contexts e.g. exercise when it is raining. See if there are situations where behaviour can be improved.

Step Two Orientation towards Problem Solving

An individuals attitude towards a problem is crucial to their success at dealing with the problem.

- The cause of the problem must be seen as changeable for successful problem solving

Problems attributed to personality or habits will be more difficult to overcome and beliefs may need to be challenged.

- Problems should be presented as challenges rather than just threats.
- Participants should be prepared to put time and effort into changing behaviours. If it was easy to change their behaviour they would have done it before now.
- It is important to increase individuals confidence in their skills to overcome

problems. This is mainly achieved by setting small achievable goals which increase their sense of success rather than failure.

Step Three Breaking the Problem Down

- The problem should be broken down into as many components as possible, i.e. each individual barrier to the behaviour should be defined.
- The participant should be able to see that a large problem can be overcome by dealing with each smaller component or barrier in turn.
- Identifying psychological barriers e.g. beliefs is as important as identifying physical barriers.

Step Four Generate Alternative Strategies to Deal with the Problem

- Barriers can be taken in turn and brainstorming can be used to identify as many different and varied strategies to deal with the barrier as possible.
- All suggestions should be considered before any are dismissed as unsuitable.

Step Five Selection of a Strategy

- Participants should choose a strategy to help them overcome their barrier
- It is important that the strategy is within the participants capabilities.
- It is better for someone to take many small, successful steps. This will increase their confidence and decrease negative feelings towards problem solving.

Step Six Using the Strategy and Evaluating Outcome

- The individual should aim to use the strategy in the coming week
- At the end of the week an evaluation of whether the strategy worked and what problems arose should be made.
- A new or amended strategy may need to be used
- The group should reinforce the individual for any positive efforts made, regardless of outcome.
- If an individual has not used a strategy successfully the facilitator should be alert to negative beliefs e.g. I will never be able to overcome this.

These steps are presented as sequential but in reality problem solving is a dynamic process and cycling between different stages may need to occur in the process of successful problem solving.

The group should be used as an asset in problem solving with all members of the group suggesting barriers and strategies that could be used to overcome any problem.

Below is an example of a problem solving discussion.

Case Example - Discussion on Dietary Behaviours

Mary states her problem is she cannot resist cakes and sugary foods. She thinks this is because she has a lack of self-control. As she attributes this to a is part of her personality she does not think she will be able to stop eating the cakes. Whenever she has tried to ban herself from eating sweet foods she has always failed.

To help Mary problem solve firstly the problem needs to be defined and broken down more fully e.g. probe the situations in which she finds herself eating these things or probe if there are any situations where it is easier to resist.

Mary explains that she looks after her grandchildren after school. She likes to bake them cakes and can't help eating some when they have some but she is not tempted during the day when they are not there.

Use this knowledge to challenge Mary's belief that she lacks self-control. Say that it could be the prompt of other people eating that triggers her inappropriate eating. Point out that she is not tempted during the day. Ask Mary and the group if they can think of any solutions to the problem.

1. *group suggest she stops baking cakes altogether*
2. *she could bake low fat low sugar cakes*
3. *she could buy cakes for the children and not store them in the house*
4. *she could ask the children to eat the cakes away from her*

Help Mary select the solution that is most suitable for her. This may be that she tries to bake low fat cakes as she feels its important for the children to have a treat after school but doesn't think they'll notice the difference in ingredients too much. She also sets a goal to allow herself to eat cake with the children on a Friday but limit herself on other days. After one week reassess Mary's progress. Use any success to reinforce the idea that it is not her personality but situational factors which are the problem.

CHALLENGING BELIEFS

For any illness an individual will hold a mental picture comprising thoughts and beliefs related to that condition. This mental picture is an important influence on behaviour.

In this programme where the emphasis is on changing diabetes self-management behaviours there are two sets of beliefs which are especially important.

i) **Beliefs about Diabetes**, i.e. thoughts about the symptoms that may be experienced, its consequences, what caused the diabetes, how long it will last etc.

ii) **Beliefs about Self-Management Behaviours,** i.e. whether an individual believes that a behaviour will influence diabetes outcomes, whether they believe they have the skills to perform the behaviour, etc.

Some beliefs both about diabetes and self-management behaviours are likely to enhance self-management, while others, especially negative beliefs may hinder it. This programme aims to promote positive beliefs towards self-management and challenge less helpful beliefs.

Common Unhelpful Beliefs are:

- **Attribution to Personality or Habits.** Individuals tend to see these factors as impossible to change.
  e.g. I'm too weak a person to stick to a diet. It's the only way I know how to cook.

- **Overgeneralization.**

e.g. Following my diet ruined the whole dinner party – the enjoyment of seeing friends is ignored because thinking is only related to negative thoughts about the diet

- **All or Nothing Beliefs.**

e.g. If I don't monitor my blood sugars 100% of the time I might as well not bother

- **Placing Excessive Responsibility on Themselves**

e.g. I don't understand what the doctor told me about the tablets because I'm stupid.

- **Jumping to Conclusions based on Insufficient Evidence**

e.g. I'm going to lose my eyesight regardless of what I do.

Such unhelpful beliefs should be challenged throughout the programme to allow a more positive context for self-management. A number of steps can be followed to help challenge unhelpful beliefs.

Step One: **Distinguish valid negative beliefs from unhelpful beliefs**.
Not all negative beliefs will be detrimental to self-management and some negative beliefs will be valid e.g. diabetes is the cause of many horrible conditions. Such a belief may even increase the probability of self-management.

It is when beliefs hamper self-management that they should be challenged.

Step Two: **Help individual identify the belief as unhelpful and possibly inaccurate**

The facilitator should never just tell the individual their belief is wrong.

Some questions will help the individual see their beliefs are unhelpful e.g.:

- Can you think of any advantages or disadvantages of thinking about the situation like this?

Other questions will help them see that their belief may be inaccurate e.g.

- What evidence do you have that supports or contradicts this belief?
- Do you think there are any other ways of looking at this situation?
- Does this apply to every situation?

Step Three: **Generate more helpful thoughts**

Ask the participant to think about whether there is a more helpful way for them to interpret the given situation.

e.g. rather than responding to a high blood glucose reading by thinking:

" This is just further evidence that I am useless at controlling my diabetes"

a more positive response would be:

" Although I am disappointed that my reading is high at least I can use this to help me understand what I may have done wrong"

Where the belief is that a behaviour can not be changed it may be useful to use problem solving skills to break barriers down into small chunks which can be dealt with gradually.

Throughout the programme unhelpful beliefs should be challenged, this will be especially important during goal setting and feed back. Participants should be prepared for failure at some goals. This will help to avoid the development of negative beliefs when a goal is not achieved. In this context it may be helpful to remind the group that:

- They are trying to break down habits that may be longstanding
- That if these behaviours were easy they would have done it long ago
- Often a failure to achieve a goal still means that they have made some changes e.g. exercising once a week instead of three times. Redefine their attempt as a partial success.

Do not let them accept that they are a failure or cannot change.

HOLDING A BRAINSTORMING SESSION

Materials Required

Large board or Flip Chart
Several different coloured marker pens
Masking Tape/Blue Tack

Brainstorming is when a topic or question is presented to a group who then suggest as many ideas or answers as possible. It is a useful technique for exploring a groups knowledge and beliefs on a topic and can be used to revise information or initiate a discussion. All individuals should be encouraged to participate in the brainstorming.

The main steps in holding a brainstorming session are described below.

Step One: Rules of Brainstorming.

It is useful to remind participants of the rules of brainstorming before starting a session. These are:

- Everyone's opinion is equally valid. Individuals should listen to each other when a suggestion is made.
- Only one person should offer a suggestion at a time
- All suggestions are valid.
- Questions and judgements on the appropriateness of a suggestion should be held until the discussion following brainstorming.

Step Two Introduction of topic and Collection of Ideas

The topic or question to be brainstormed should be written on the top of the flip-chart/board.

Participants should be prompted to present as many ideas as possible. All suggestions should be written down. Value judgements should not be made on suggestions at this stage.

Step Three Clarification of Suggestions

Ask the group if everyone is happy with what is meant by each suggestion. Where issues arise ask the individual who made the suggestion to explain what they meant. The leader should avoid making interpretations unless the participant has difficulty explaining.

Step Four Discussion of Inappropriate Suggestions

Incorrect information or unhelpful beliefs may become apparent during brainstorm. It may be useful to ask the group whether everyone agrees with an inappropriate suggestion. This is a non-threatening method for correcting misunderstandings or challenging beliefs. It is important not to be dismissive of incorrect suggestions or simply tell the participant they are wrong without exploring why they hold a belief.

Step Five General discussion of topic

The ideas presented in brainstorming can be used as a basis to revise or discuss a topic.

It may sometimes be appropriate to cycle through the steps of brainstorming when discussing different aspects of a large issue. For example in discussing barriers to diet it would be possible to brainstorm i) practical barriers ii) strategies to overcome practical barriers, iii) emotional or social barriers, iv) strategies to overcome emotional or social barriers

Tips for Brainstorming

1. Use different colour markers to denote subtopics
2. Have two facilitators run a session, one to collect ideas the second to write them up
3. If a participant is dominating the group ask them to write up suggestions
4. Pin-up additional pages from the flip chart if many suggestions are made

GOAL SETTING

Materials Needed

Goal setting sheet (1 per person)
Pens/Pencils

Goal setting is where individuals set a behavioural target to be completed in the coming week. The aim is to demonstrate to the individual that they are capable of behaviour change when made in small steps. Goal setting is an important tool for increasing an individuals self-efficacy and general sense of control over their diabetes.

Several Principles should be followed when assisting individuals to set a goal.

1. Goal Setting Should be for Short Term Goals

The aim is to set a goal that can be achieved within the coming week. It is useful to distinguish between long-term, intermediary and short term goals as below.

Long Term Goals - These tend to be for some time in the future and require considerable behaviour change. How these changes will be made is not well specified.
Examples of long term goals

1. *For blood sugar to be <7.5*
2. *to lose 2 stone in weight*
3. *to be able to take part in BDA walkathon*

Intermediary Goals – These deal more specifically with the behaviours that need to be changed but are still relatively vague and removed from present behaviour levels.
Examples of Intermediary goals

4. *to reduce fat in diet*
5. *to exercise every week*

Short Term Goals – These are very specific and describe the behaviour change in detail. Goals are obtainable from the individuals present status.

6. *to poach rather than fry eggs*
7. *to walk twice around the block on every other day*
8. *to monitor blood sugars each morning after cleaning teeth*

2. Goal Setting Should be at an Appropriate Level

The aim is for individuals to succeed at their goal and therefore increase their self-belief in behavioural change.

Goals should be set at a level the individual is approximately 80% confident of being able to achieve. Generally it is better for someone to set a goal for 3 or 4 days of the week rather than 7. This decreases the risk of failure

3. Goals Should Consider a Person Readiness to Change

Readiness to change is how prepared someone is to change their behaviour. Commonly there are 5 levels of readiness to change. These are:-

i) not performing a behaviour and not intending to begin.
- a suitable goal may be to make a list of the pros and cons of the behaviour

ii) not performing a behaviour but intend to begin doing so

iii) performing the behaviour sometimes but not on a regular basis

iv) performing the behaviour on a regular basis but for less than 6 months

v) performing the behaviour on a regular basis for greater than 6 months
- a suitable goal may be to think of when the behaviour is difficult and make a plan for these occasions.

4. Goals Should Be Defined in Detail

Four things should be stated for any goal:

i) What is going to be done (eat more fruit/ increase walking)

ii) How much (two pieces of fruit/ walk around block twice)

iii) When (after lunch and after dinner/ during lunch break)

iv) How often (on Monday, Tuesday, Thursday, Friday)

5. A Contract Should be Made of the Goal

Once the goal setting sheet is completed the individual should sign the base of the form and hence enter into a contract with the rest of the group.

The facilitators role in goal setting is to ensure appropriate and well defined goals are set. A facilitator should not however set goals for individuals, these must be self-selected.

Goal Setting Sheet

Name: Date:

Self-Management Behaviour: .....

My goal for this week is to:
.....

This consists of (how much)
.....

I will do this (when)
:.....

I will do this (how often): .....

I rate my confidence at completing this goal as ..... given a scale of 1-10 where 1 is completing unconfident of completing the goal and 10 is completely confident of completing the goal.

I agree with the rest of the group to perform the goal described above in the following week.

Signed:.....

REINFORCEMENT

Materials Needed

None

If a behaviour is followed by a pleasant experience it is more likely this behaviour will be followed in the future. This is called positive reinforcement.

In this programme two types of positive reinforcement are used:

- **Facilitator/Group reinforcement** - Where an individual has made positive efforts towards self-management behaviours both the facilitator and group should commend their efforts. Encouraging participants and praising positive aspects of even a failed goal is important.

Facilitator Reinforcement

Thank you Abdul for telling us how you got on with your diet last week. You say that you were disappointed that you let yourself eat Chinese take-away for dinner on Wednesday. Even though you did this you still choose plain rice and included vegetables which is good, but maybe we can help think of ways to stop yourself being tempted to get take-away in the future.

- **Self-reinforcement** - Individuals select rewards to receive if they are successful at their goals. Rewards should not be expensive but something simple that can fit into everyday life. Participants should be discouraged from choosing food as a reward as this may be detrimental to dietary behaviour.

Example Rewards

Lottery Ticket
Trip to the cinema
Save money from not buying biscuits to spend on magazine/flowers

THE GROUP PROCESS

The programme is designed to be run in small groups with the group leader acting to facilitate the group process. While the content of sessions is described in detail there are a number of general points that will assist in the successful running of a group.

Facilitate vs Educate – The role of group leader is not to lecture in a traditional educational model but to facilitate group strategies so that information and strategies to deal with problems are drawn from within the group.

Modelling – Before any exercise it is good practice for the group leader to model the behaviour that is being requested of individuals. Therefore in goal-setting the facilitator could describe an example goal or in brainstorming give examples of the sort of information that is requested from the participants.

Silence – It is likely that at times there will be silence within the group, either in response to a question or exercise. This can feel uncomfortable to the facilitator and the temptation may be to respond by providing the answer/information to participants. Where possible this should be avoided, as if left the silence will probably be broken by a member of the group. If this looks unlikely, probes should be used to encourage the group to contribute. It should be remembered that what may appear as silence to the facilitator will simply be thinking time for the group.

Wrong Answers – If a participant offers information which is incorrect then the facilitator can correct misunderstandings, but care must be taken not to undermine the participant. A more difficult situation may be if a participant presents an unusual belief. The facilitator should acknowledge and validate the participant's belief, but may then use this as a basis for further discussion.

For Example:
That's an interesting point Rose. Does anyone else think about ... in the same way? Does anyone else have other ways of looking at the subject?

Talkative Participants – Within any group it is common to find one or two individuals who wish to dominate. These participants must be controlled so that other members of the group can be allowed to contribute. Effective ways to do this include:

- Withdrawing eye contact from the person when asking for responses from the group.

- Giving the person a task such as acting as scribe during brainstorming sessions.
- Actually telling the participant that while their contribution is very useful you'd like to hear from some other people as well.

This sort of individual can actually be used quite effectively when a difficult exercise is being completed which requires a confident individual to make the first contribution.

Quiet Participants – The opposite of the dominating participant is the individual who avoids any contribution to the group. In this situation the facilitator should:

- be alert to any non-verbal body language that the participant may like to contribute.
- draw the individual into the group in exercises where everyone has to contribute, by going around the group.
- request a contribution when the participant knows their answer will be correct.

The participant should never be put on the spot or a response demanded as this may undermine confidence and prevent any further contributions.

Inappropriate Language/Behaviour - If an individual makes contributions which are inappropriate or offensive to other members of the group then this should be dealt with immediately. The individual can be reminded that at the outset everyone agreed to the rule of listening and respecting other peoples contributions. If there remains a problem with an individual it may be necessary to take them aside during the break or after the session and explain that their behaviour is inappropriate. If this still does not resolve the problem and their behaviour is continually disruptive to the group the only option may be to ask the individual to leave the programme. However, this should only be used as a last resort.

SESSION ONE

Session One - Objectives

By the end of the session each participant should:

- have introduced themselves to the group
- be aware of the aims of the programme
- be able to explain what diabetes is
- be able to state that an important reason to have good blood sugar control and blood pressure control is to reduce complications
- be able to explain what self-management means, and that it is an important tool for improving blood sugar control
- be able to name six self-management behaviours
- have demonstrated their ability to test their blood sugar correctly
- be able to define hypoglycemia
- have set an individual goal for blood sugar testing or other behaviour of patients choice

Session One – Content

1.1 WELCOME (5 minutes)

Aim: *For every individual to briefly say something within the group.*

- Welcome people to the course.
- Introduce yourself.
- Explain that you will be working together with the group over the next few weeks.
- State what your experience is and validate why you are in a position to help people with diabetes.

Example

"Although I don't have diabetes I've worked as a practice nurse for – years and over that time I have meet many people with diabetes who have shared their experiences with me."

- Ask patients to introduce themselves using the following question.

Question: **I would like you each to tell the group your first name, how long you've had diabetes and what treatment you use to control your diabetes.**

Summarise:

- **Everyone here has some things in common** i.e. you all have diabetes.
- **Everyone also has differences** i.e. length of time you've had diabetes or what treatment you are on.
- These similarities and differences will **help us to understand each others problems.** They will also help us to **offer different points of view** about how to deal with these problems.

1.2 EXPECTATIONS OF THE PROGRAMME (10 minutes)

Aim: *To discuss what the programme will be like and to discover the aims and expectations of participants.*

- Tell participants that you would like to briefly discuss what the programme will be like.
- Ask question, then summarise information.

Question: **Does anyone already have thoughts on what they expect the programme to be like, or what they hope to get from the programme?**

Summarise:

- The programme is about living with diabetes.
- The programme aims to help you **learn skills that will make living with diabetes easier.**
- It aims to **increase your feelings of control** over your diabetes.
- This sense of control can **help to improve blood sugar levels** and hence **reduce the chance of long-term complications.**
- The **skills** that will be taught **will sometimes be practical** (e.g. selecting a correct diet), but will **sometimes be more general** e.g. identifying strategies to deal with problems.
- The **emphasis is on group participation**. Learning will mainly be through **group discussion and exercises**, where everyone will have the opportunity to contribute.
- You are the experts on living with diabetes. The **aim is for you to be able to learn from each other as well as from me**.

- The aim is for **everyone to feel equal** and to be able to speak about their own difficulties or successes.

- Living with diabetes can sometimes be difficult. The aim of the programme is to help people recognise and overcome these difficulties, rather than to judge people.

- Overall, the programme is **designed to help you as individuals**. All that is requested is commitment to attending, and giving the programme your best efforts.

1.3 GROUND RULES (5 minutes)

Aim: *To establish ground rules, which all group members will adhere to.*

- Tell participants that to get the most out of the group it is useful to set some basic rules. This ensures everyone knows what to expect from the group and what can be expected of them.

- Tell participants the following information then ask the question.

Information:

- You will all get the most out of the programme if **everyone comes regularly.**

- We ask that **if you are unable to attend, e.g. if you are ill, that you let us know by calling us**. This is important because it stops the group from worrying and allows us to make any necessary changes to the session.

- Much of the programme is group discussion, so we ask that **everyone shows respect when others are talking**. People may have different opinions and this will be a good thing, but we all need to know that we will be listened to when we talk.

Question: **Would anyone like to suggest any other rules or ask any questions?**

- Discuss any suggested rules and answer questions.

1.4 WHAT IS DIABETES? (30 minutes)

Aim: *To understand what patients know about diabetes. To ensure a basic understanding of why diabetes is serious and needs to be controlled*

- Say you would like to start by revising what diabetes is. This will ensure that everyone is at the same starting point.
- Tell the group that to revise this information you are going to have a brainstorming session. Explain the concept of brainstorming.
- Use information from the initial brainstorm to go through a description of diabetes including complications. Use additional probes if necessary.

N.B Although this seems a lot of information it should not be new, hence it can be moved through quickly. Most information should be covered by participants and just structured by facilitator.

Question: **What comes to mind when you think about diabetes?**

Diabetes is:

Probe: **- Can anyone tell me more about what happens in the body with diabetes?**

Summarise:

- Diabetes is when the **level of sugar(glucose) in the blood is too high**.
- This is because there is **not enough insulin** produced by the pancreas, or because the **cells of the body do not recognise insulin adequately (insulin resistance).**

- **All cells in the body need energy** to be able to work.

- They get this **energy from sugar,** which is transported to the cells by the blood.

- Just as you need a key to open a door, cells need insulin to open a pathway before the sugar can go in. **Insulin acts like a key to allow sugar to pass from the blood into the cell.**

- Insulin resistance is when the lock and key don't fit together properly.

- **In diabetes** because i) there is **not enough insulin** or ii) the **cells do not recognise the insulin**, sugar tends to collect in the blood rather than being used by the cells.

<u>Types of Diabetes</u>

Probe: **- Does anyone know what different types of diabetes there are?**
- How do these types of diabetes differ?

Summarise:

- Point out that **everyone here has type 2 diabetes**

- This means that you may **still produce some insulin** but either the cells are not as sensitive as they used to be or you are not producing as much insulin as you used to.

- This type of diabetes is sometimes called **non-insulin dependent or maturity onset diabetes.**

- The **other type of diabetes is type 1diabetes**, or insulin dependent diabetes. This is normally developed as a child or young person and is where no insulin is produced. All these patients have to take insulin

- Type 2 patients may also need to use insulin as a way to improve their blood sugar control.

- Type 2 diabetes is sometimes also referred to as mild diabetes, but **both types of diabetes are equally serious.**

What causes type 2 diabetes?

Probe: **- Do any of you have ideas about what caused your diabetes?**
- Who tends to get diabetes?
- Has anyone ever felt it was their fault they got diabetes?

Summarise:

- The **cause of type 2 diabetes is often unclear** but we do know that there are certain things that increase the risk of developing diabetes.

- **Age.** This can vary. Generally Western or Afro-Caribbean patients are likely to be over 40 years of age but amongst Asian populations it may be common to develop type 2 diabetes between 30-40 years of age.

- **Being overweight** is a factor.

- Sometimes diabetes will run in the family, there is a **genetic link.**

- Also different **ethnic groups** have higher risks of diabetes especially Asian or Afro-Caribbean individuals.

- The most important thing to remember is that it is **nobodies fault that they have diabetes**, so blaming someone is wrong.

- **But individuals can play an important part in controlling their diabetes and in influencing outcomes once they have it.**

Question: **What happens when you have diabetes if you do nothing to treat it?**

Probe: **- Can you remember what symptoms you may have experienced when you were first diagnosed?**

Short-term – Symptoms

- If your blood sugar is high or poorly controlled it is likely that you will experience some symptoms. These will probably be similar to those that you may have experienced when you were first diagnosed and may include:

- **Tiredness**

- **Frequent urination** - this is because a lot of the sugar overflows into the urine and draws out water with it.

- **Increased thirst** – the body loses more water because of the frequent urination and this in turn makes you thirsty.

- Explain that these symptoms are all **caused by blood sugar being too high**, although not all people get symptoms when blood sugar is high.

Long term Complications

- This is some of the most critical information to come from the brainstorming. The essential message to convey is that there are serious implications of diabetes but that these can be avoided if care is taken.

- Use overhead 1.1 to go through each complication. This does not need to be in too much detail. The aim is to make people aware of the serious nature of diabetes.

Question: Has anyone heard of longer term problems that can occur with diabetes?

Overhead 1.1 (indicate that there are four main areas of the body affected by complications)

Problems with the eyes (retinopathy)

Probe: - Does anyone know how diabetes affects the eyes

Overhead 1.2 (briefly explain the structure of the eye, i.e. point out the lens and retina)

Summarise:

- Having diabetes means that you are at increased risk of having problems with your eyes.

- Diabetes can affect your eye-sight in a number of ways:

- I) The **risk of cataracts is increased** which is when the lens becomes cloudy.

- II) The **blood vessels in the retina can become damaged**. This is what the doctor looks for when he looks in the eye.

- It is therefore **important to have regular eye checks** because if detected early enough damage can be treated with lasers. *(Ask if anyone has had laser treatment.)*

Problems with the Heart and Blood Vessels

Probe - How does diabetes affect the heart and blood vessels?
- What does this increase the risk of?

Overhead 1.3 (use to show blocked vessels)

Summarise:

- The role of the heart is to pump blood around the body; the blood passes into the heart via veins and out of the heart via arteries.

- Sometimes the **blood vessels** supplying blood to the heart can **become blocked**.

- This can **cause chest pain called angina** and can **cause heart attacks.**

- Having **diabetes increases the risk** of having these sorts of problems.

- However, many of your medications and self-management behaviours will help to reduce the risk or improve the outcomes of heart disease.

- They will also help to reduce the risk of stroke which is increased with diabetes.

- Stroke is when a blood vessel in the brain becomes blocked.

Problems with kidneys (nephropathy)

Probe: **- In what way does diabetes affect the kidneys?**

Summarise:

- Just as diabetes can cause damage in the eye it can also cause damage to the small blood vessels in the kidney.

- Again this can be tested for and damage can be prevented by controlling blood pressure and blood sugar levels.

Problems with the feet

Probe: **- Does anyone know how the feet are affected by diabetes?**

Summarise:

- People with diabetes can have difficulties with their feet. This occurs for two reasons:

- I) **Diabetes can make the nerves in the feet less sensitive** to things like heat or touch (peripheral neuropathy).

- II) **The blood flow to the feet can be poor**.

- The result of these two factors mean it is more likely for someone with diabetes to damage their feet and not notice it. Once damaged, it can be difficult for this area to heal especially if blood flow is poor.

- At the most serious level gangrene can develop which may lead to amputation. Again, there are many things that you can do to prevent this from happening and we will be discussing these later.

Complications general points

Probe: **- What are the main causes of these complications?**
- What can be done to reduce the risk of developing complications?
- How does the thought of complications make you feel?

Summarise:

- **Complications can be a frightening** part of diabetes, but it is important to understand that diabetes can have serious implications.

- It is not good for blood sugar or blood pressure to be high. If left uncontrolled or running too high then complications may develop.

- There are things you can do **to decrease the risk of complications:**

- A) **Always attend your annual review**. This keeps track of complications so that they can be detected and treated early.

- B) **Control your blood sugar and blood pressure levels**. You can do this by following self-management recommendations which is what this programme is focussed on.

- We now know that even people with relatively good control can benefit from tighter blood sugar and blood pressure control.

Explain the following points to the group:

- The programme is going to look at what self-management behaviours help control blood glucose and blood pressure and will also look at the wider issues of living with diabetes e.g. how things like moods and feelings or social situations influence the control of diabetes.

- It will look at situations in which it is most difficult to follow a diabetes regimen, and how to deal with these situations.

- It will also consider how diabetes can be managed without it dominating your life.

- Overall, it is hoped that if you can learn to control your diabetes, and feel in control of your diabetes, then this will improve your quality of life for both now and the future.

1.5 WHAT DO WE MEAN BY SELF-MANAGEMENT AND WHY IS IT IMPORTANT FOR DIABETES? (10 minutes)

Aim: *To identify what the main self-management behaviours are in diabetes and to explain how these will be the focus of the rest of the programme.*

- Ask question. Use the responses as a basis to define self-management.

- Hold brainstorming session to identify those self-management behaviours appropriate to diabetes.

- Give a general overview of the way self-management behaviours will be looked at in the programme.

Question: **What does the term self-management mean to you?**

Summarise:

- Self implies you as an individual, management implies taking control of something.

- **Diabetes self-management means you taking control of your diabetes.**

- Although you may take on the main management role **this does not mean you are alone**; doctors, nurses, family etc still play an important role in supporting you.

- The **key to self-management is self-management behaviours**.

Question: **What self-management behaviours can you think of for looking after diabetes?**

Probe: **- Can you think of any others?**
- Are there any habits you have been told to give up?

Summarise:

- ❑ Diet
- ❑ Exercise
- ❑ Urine or Blood sugar testing
- ❑ Taking medication, tablets or insulin
- ❑ Checking feet
- ❑ Giving up smoking
- ❑ Wearing an identification card/bracelet

- Over the next 5 weeks we will be talking about these behaviours

- While there may be some revision, the programme will be looking more at the highs and lows of carrying out these behaviours and how they fit in with your everyday lives.

- One **aim is to see how all the behaviours interact together** to influence blood sugar and blood pressure control and your feelings about living with diabetes.

- **Remember you are the experts on living with diabetes** and will all find different behaviours easier or more difficult to do. The benefit of working in a group is everyone can share these experiences.

COFFEE BREAK (10 minutes)

1.6 HOME BLOOD GLUCOSE MONITORING (HBGM) (35minutes)

Aim: *To ensure that participants know why HBGM is important. For patients to revise or learn how to do HBGM and to understand what the results mean.*

- Use question to identify who uses blood sugar monitoring and how often they have been told to do so.

- Follow with brainstorming session and summarise why monitoring is important

Question: **I would like everyone to say whether they monitor their diabetes, how you do this e.g. blood sugar testing or urine tests, and roughly how often you do this.**

Summarise:

- Most people have had some experience with monitoring (testing) but the type of monitoring and frequency can differ depending on treatment.

- Urine testing looks to see if sugar has overflowed into the urine. This only happens when blood sugar is quite a bit higher than it should be.

- To get better blood sugar control we really need to use blood sugar monitoring (testing).

- The **goals for frequency of monitoring (testing) will vary between individuals**.

- But regardless of how frequently you monitor (test) it still plays the same important role.

Question: **Does anyone have any ideas as to why monitoring (testing) blood sugars is important?**

Summarise:

- **HBGM gives an immediate indication of blood sugar levels** at that precise moment.

- This can be **helpful in making decisions about behaviours** that you intend to carry out.
  e.g. if you need to eat something before doing the gardening

- It can also **help you to see the impact of behaviours** you have recently completed.
  e.g. how high was my blood sugar after eating a piece of cake?

- When blood sugars are recorded regularly you can also look for patterns and think about how these patterns relate to any change in behaviours.
  e.g. you may notice that giving insulin in the evenings makes your blood sugars a lot lower

- Overall **HBGM allows you to take control of you diabetes** by giving you a window on your blood sugars and how they change with your behaviour.

- Tell the group that you are now going to show people how to monitor and will then check that they can do this accurately.

- Emphasise to people who test regularly that this is still useful because it is always easy to fall into bad habits when you do something very often- just think about your driving habits now compared to when you passed your driving test.

- Give practical demonstration on self as below.

- Split group into testers and non-testers and complete practical.

Practical: **Take a measurement of blood sugar**

Step 1 – Facilitator demonstration

i) Wash hands in warm water

ii) Prick side of finger with lancer device

iii) Follow guidelines of individual machine

iv) Record result in monitoring book – explain that recording the result allows individuals or their doctors to check for patterns in their blood sugars. Suggest that it can also be useful to record any unusual events that you think may have influenced blood sugars

Step 2 – Patient Practice

i) Teach or check method for each individual until performed correctly.

ii) Reinforce patients for successful monitoring (see reinforcement sheet).

iii) Distribute monitoring books if required; ask patients to record reading.

1.6a WHAT DO THE RESULTS OF HBGM MEAN? (a-d 15 minutes)

Aim: *To discuss what different blood sugar levels indicate, including hypoglycaemia. Explain how these results are different from HbA1c.*

- Use the questions below to help explain the results of HBGM

Question: **Does anyone know the normal range of blood sugars for people <u>without</u> diabetes?**

Probe: **- What should they be in people with diabetes?**

Summarise:

- Levels in individuals **without diabetes range from 4.0- 8.0mmol/l**

- For people with **type 2 diabetes** blood sugars are usually higher than this but the **aim is to be as close to this level as possible.**

- Write up a range of blood sugar values on flip chart.
- Indicate those readings that are close to the ideal level and those which are too high.
- Explain that a number of factors influence momentary blood sugar measurements e.g. eating tends to raise levels and exercise tends to lower levels. Say that you will be looking at these interactions in the coming weeks.

1.6b WHAT IS HYPOGLYCEMIA?

- Indicate low blood sugar level from flip-chart and ask question.

Question: **What does this reading mean?**

Probe: **- What might have caused this blood glucose reading?**

Summarise:

- Blood sugars which are too low, **below 4.0**, indicate hypoglycaemia. **Remember "four is the floor"**

- Hypoglycaemia is mainly a risk if you are taking insulin although it can occur with some tablets.

- **Hypoglycaemia occurs when the balance of medication (insulin or tablets), food and exercise are not quite right.** This usually occurs if insulin is too high, if you have missed a meal, if you have increased your exercise, or sometimes if you have been drinking alcohol.

- Often the problem is having eaten differently from normal. Remember the phrase **" think food first"** to remind yourself to think about what you have eaten recently.

Question: **Has anyone experienced hypoglycaemia? Can you tell us what symptoms you experienced?**

Summarise:

Common symptoms are:

Shaking/Trembling
Heart Beating Faster
Loss of Concentration
Sweating
Feeling Irritable
Mood Swings
Headache

- **Symptoms vary between individuals** and not all individuals will experience symptoms.

Question: **If you thought that your blood sugars were too low what would you do?**
Probe: **- What would you use to treat it?**
- Does anyone else have any ideas?

Summarise:

- **If you think your blood sugars are too low you should ideally test your blood sugar level.**

- If the reading is **below 4.0 mmol/l treat immediately** by eating or drinking something which is sweet and can be absorbed quickly e.g. fruit juice or taking 3 dextrose/sugar tablets.

- If you can not test your blood sugar but **think it may be too low treat it anyway.**

1.6c HbA1c TESTING

- Explain the difference between HbA1c and HBGM providing the information below.

N.B. Optional information may be too complex for some groups

Question: **What do you know about the HbA1c test?**

Probe: **- What do you think this reflects?**

- How do you think this is different from the results of your finger prick test?

Summarise:

- HBGM measures the amount of sugar in the blood at the moment that you do the blood test.

- **Another measure of blood sugar control is called the HbA1c test.**

- This comes from the blood test you have at the hospital and gives an average picture of how well your blood sugars have been controlled over the last 6-8 weeks.

- What can be confusing is that the **figures for HbA1c and HBGM are very similar.**

- For example, people without diabetes have an HbA1c of 4.0-5.7%.

- Again, people with diabetes should **aim for an HbA1c reading as near to normal as possible, and at least below 7%.**

- For the purposes of this programme we will be talking mainly about home blood sugar testing, that is the blood sugar which you measure and record yourself from day to day.

(optional information)

- *in the red blood cells there is a substance called haemoglobin which sugar attaches to.*

- *When a blood test is taken, it is possible to measure how many of the red blood cells has sugar attached to it. This is measured as a percentage. Because red blood cells live for 3-4 months, and on average will have been in the blood for 6-8weeks, it gives an average measure of how well blood sugars have been controlled.*

1.6d HOW FREQUENTLY SHOULD HBGM BE PERFORMED?

Probe: **- How often do you think you should test your blood sugars?**
- When would be good times to test your blood sugars?

Summarise:

- Explain that this is **partly dependent on treatment** e.g. if prescription is diet and exercise alone or tablets, twice a week may be enough.

- If you are on insulin it is usually recommended to monitor twice a day as blood sugar levels can vary more when you are on insulin.

- These are only guidelines however, and for every individual the frequency of blood testing may be different.

1.7 GOAL SETTING (15 minutes)

Aim: *Explain the general principles behind goal setting. Help each individual to set a specific goal for a behaviour of their choice.*

- Explain to the group that they will now set a goal. Suggest that HBGM may be appropriate as it is what has been discussed but it can be on anything e.g. reading more about diabetes care etc

- Explain principles and point of goal setting as on technique sheet. Ensure the following concepts are explained:
  - Long term vs short term goals
  - Specificity of goals
  - Confidence in completing goals
- Help each individual to set a behavioural goal for the coming week.

- If setting goals for monitoring established monitors may find it useful to monitor at different times from their normal pattern, or after certain behaviours e.g. exercise. If possible let the individual select when these different times should be.

- Ask participants to complete the goal setting sheet

- Ask each individual to tell the group what goal they have set and how confident they are about achieving this.

1.8 SESSION CLOSE

- Inform participants that next week you will begin by seeing how people got on with their goals. Say that you will look at any problems individuals may have had and ways of overcoming these problems. Tell the group that you will also begin to look at the role of food in diabetes.

- Remind group to contact facilitator if they cannot attend.

Overhead 1.1

AREAS OF THE BODY WHICH CAN BE AFFECTED BY DIABETES

Overhead 1.2

THE EYE

Overhead 1.3

BLOOD VESSELS

SESSION TWO

Session Two - Objectives

By the end of the session each participant should:

- have had the opportunity to identify a strategy to deal with difficulties related to monitoring
- be able to state that both emotional and social contexts, as well as hunger, influence eating
- be able to name 5 reasons why food plays an important role in diabetes
- be able to list the five main food groups and identify typical foods from each group
- be able to list principals of a healthy diet
- be able to identify strategies for following the principals of a healthy diet
- have set at least one short-term behavioural goal and selected a reward for completing the behaviour

Session Two - Content

2.1 INTRODUCTION (2 minutes)

Aim: *To describe the main content of the session.*

- Tell the group that today's session has two main topics.
- I) Monitoring and dealing with problems associated with monitoring.
- II) Food, including the role that food plays both in day to day living and in relation to diabetes.
- Say that you would like to begin by hearing how people got on with last weeks goal.

2.2 GOAL SETTING FEEDBACK (8 minutes)

Aim: *For each individual to speak within the group. To hear and reinforce the groups efforts with their goals.*

- Ask participants to provide feedback on their goal from last week using the question below. Emphasise that it is important for individuals to start with a positive comment before mentioning more difficult experiences.
- Thank each participant for their response. Reinforce each individual for their effort, regardless of outcome.
- If an individual mentions a problem write this on the flip-chart. Tell the group that you are going to look at how you can overcome problems with monitoring in a moment once everyone has given feedback on their goals.

Question: **Let's go around the group and can each person remind us what their goal was and how they got on. Say what you managed and whether you had**

any problems.

2.3 BARRIERS TO HOME BLOOD GLUCOSE MONITORING (15 minutes)

Aim: *To discuss problems or situations where it is difficult to follow monitoring advice. Identify strategies for dealing with problems and challenge false or inappropriate beliefs.*

- Indicate that some problems related to monitoring were mentioned during goal feedback. Brainstorm any other monitoring problems.
- Use the probes below if these issues are not raised independently.

For example: John, Edward and Joan you all mentioned that one problem was the pain of pricking your finger, did any one else find this?

Question: **Can we now list any other things that make it more or less difficult to complete your monitoring as required?**

Probe:

- **Does anyone else have other ideas?**
- **Does anyone ever find they just forget to monitor/ are too busy to monitor? In what situations does this happen?**
- **Some people have said they prefer not to monitor as they would rather not know their reading. Does anyone here ever feel like that?**
- **Are there any situations in which you try to avoid monitoring?**
- **How would you find monitoring if you were eating out or in a social situation?**

- Having exhausted brainstorming take each problem in turn and brainstorm strategies to help deal with the problem. Use probes if the group can not identify appropriate strategies.
- Begin with practical problems then move on to emotional problems e.g. avoidance of results.

- Where an individual identifies that they had a specific problem ask them to select one of the strategies to try.

For Example: Julia you said you found it difficult to remember to monitor when staying at your daughters, do you think any of the strategies that we have mentioned could be useful for you?

Question: **Let's take (problem X), can you think of any strategies to deal with this?**

Probe: **- Are there any times when it is less painful?**

- Has anyone else found something that helps them remember to monitor?

- What would make you less embarrassed about testing?

Problem	**Strategies**
Pricking finger is painful	- prick the side of the finger - warm hands first
Forgetting to monitor	– use reminders – ask partner to remind – link to other behaviours e.g. after cleaning teeth
Embarrassed to do at work	– ask boss if there's a separate room that could be used – arrange to monitor before going to work
I would rather not know my blood sugar level (N.B challenging belief appropriate)	- consider why they would rather not know, problem solve the reason for this

- Explain that you need to move on from monitoring. Before you do ask if anyone wants to amend the goal they set last week, possibly to include a strategy to help deal with a problem.

- Help any individuals who wish to reset their goals.

2.4 FOOD AND DIABETES – INTRODUCTION (10 minutes)

Aim: *For participants to consider the role that food plays in everyday life. For the group to consider the social and emotional as well as functional roles of food.*

- Say you will now move on to the topic of food and its role in diabetes.
- Emphasise that throughout the sessions when you use the term diet you are not talking about a weight loss or calorie counting diet but rather a method of healthy eating. Most of this information will be applicable to people with and without diabetes.
- Begin by using a brainstorming session to identify reasons for eating. It is important that individuals are probed to identify the social and emotional reasons. Use the probes below if these issues are not raised independently.

Question: **Can you name the different reasons that lead us to eat food?**

Probe: **- What sort of feelings or emotions lead you to eat?**
- Are there any situations where you eat even though you might not be hungry? (e.g. part of routine, social events)

Summarise:

- What, and how we eat, can be influenced by mood, social situations and habit, not just hunger.
- To successfully follow a healthy diet we need to take all these factors into account. Therefore we need to know:
- a) what foods are suitable for us to eat
- b) how our feelings and situations influence our eating habits

- c) how to cope with situations where our life and healthy diet do not always fit together

- Tell the group that today you will begin by revising information on different food groups so that everyone has the same starting knowledge.
- Point out that over the years information has changed so you also want to bring everyone up to date with the latest knowledge.
- Say that next week you will look at how to follow a healthy eating plan even when the situation e.g. social/emotional context makes it difficult to do so.

2.5 THE IMPORTANCE OF FOOD IN DIABETES (5 minutes)

Aim: *To cover why food is an important topic for diabetes*

- Begin by brainstorming the main reasons why food is important in diabetes

Question: **What are the main reasons that food plays an important role in diabetes?**

Summarise:

- What we eat can **influence blood sugars**
- It can **influence weight loss or weight gain**
- It can **influence the risk of cardiovascular(heart) disease**
- It can **influence blood pressure**

- Emphasise that what you eat has an important impact on the outcomes of diabetes, and that this impact tends to vary from food to food.
- Say that to understand which foods have beneficial effects and which are likely to cause problems it is useful to split foods into food groups.

2.6 FOOD GROUPS (15 minutes)

Aim: *Revise main food groups & their implications for diabetes*

- Use the questions and probes to help the group work through the following information.
- Confirm that you know it will just be revision for many members.
- Clarify any misconceptions by challenging beliefs, using the group as appropriate.
- Complete exercise one to reinforce knowledge.

Question: **What are the main food groups that you have heard of?**

- Write food groups on flip-chart as they are mentioned then take each in turn and discuss their importance to diabetes and examples.

STARCHY FOODS/ CARBOHYDRATES

Question: **What are some examples of starchy foods?**

e.g. bread, potatoes, pasta, chapattis, plantain, yam, cereals, rice

Probe: **- Why are starchy foods important in our diet/ for diabetes?**
- How often should you eat starchy foods?

Summarise:

- These are one of the **most important food groups for people with diabetes.**
- Their main role is to **give the body energy.**
- People with diabetes are encouraged to eat starchy foods at every

meal, and they should be the main part of your meal.

- Some types of starchy foods are better than others because they are **more slowly absorbed by the body.**

- Examples of these are pasta, basmati or easy cook rice, wholegrain bread, green banana, yams, porridge oats, branflakes, all bran.

- More slowly absorbed foods can help to **control your blood sugars.**

- Starchy foods can also help **fill you up**, which will help if you are trying to lose weight.

- Starchy foods can also be high in fibre which is good for keeping bowels healthy.

FRUIT AND VEGETABLES

Probe: **- Why are fruit and vegetables important for your diet?**
- How much fruit and vegetables do you think you should eat a day?
- Are there any fruits or vegetables that you think you should avoid?

Summarise:

- Another food group that all people, including those with diabetes, should eat regularly is fruit and vegetables.

- These are an important **source of vitamins and minerals.**

- They are **high in a form of fibre that can help control blood sugars and lower cholesterol.**

- You should aim to **eat at least 5 portions of fruit & vegetables each day.** These should be spread throughout the day.

- One portion would be 1 piece of fruit e.g. apple, banana, a handful of

grapes or 1 serving spoon of vegetables.

- Fruit juice, even unsweetened, can cause blood sugar to rise quickly so you should only drink one small glass per day.

- Tinned fruit in water or natural juice are better choices than those in syrup.

- All fruits and vegetables are included within this group except potatoes, yams and plantain which are considered starchy foods.

- People with diabetes can eat any kind of fruit.

PROTEIN

Question: **What are examples of foods containing protein?**
e.g. meat, fish, egg, beans and pulses, lentils, cheese

Probe: **- In what way is protein important to the diet?**
- What types of food are particularly good sources of protein?

Summarise:

- Protein is used to **repair damaged cells or for the growth of new cells.**

- It has a **small impact on blood sugars**.

- Beans, pulses and lentils are a good source of protein because they are low in fat and being starchy are also slowly absorbed.

- Some sources of protein, like cheese and red meat can be high in fats, so beans, pulses or fish are better options.

FATS

Probe: **- What do you know about fats?**

- What sort of fats have you heard of?

Summarise

- Fats play an essential role in the diet as they **transport vitamins and minerals.**

- But fats are **high in calories** and tend to be associated with weight gain which in turn makes it harder to control diabetes.

- Also some fats are associated with an **increased risk of heart disease.**

- There are 3 main types of fats:

❑ SATURATED FATS

- These mainly **come from animals**, with the exception of palm and coconut oil.

- They tend to be **hard when cold**, e.g. butter, lard.

Question: **Can you think what types of food contain saturated fats?**
e.g. cheese, full fat milk, butter, fatty meat or poultry with skin on

❑ UNSATURATED FATS

- These are called **polyunsaturated fats** e.g. sunflower oil or **monounsaturated fats** e.g. olive oil.

- They tend to be **liquid when cold.**

Question: **What examples of unsaturated fats are you aware of?**
e.g. mono/polyunsaturated margarine, oily fish, olive oil, peanuts

- ❑ CHOLESTEROL
- Another type of fat is called cholesterol
- This is a fat substance **found in the blood.**
- There are good and bad forms of cholesterol.
- **Bad cholesterol** is associated with saturated fats and raised levels are **associated with heart disease**. Therefore **saturated fats should be reduced.**
- **Good cholesterol** comes from **hydrogenated fats** e.g. oily fish, functional foods (pro-active).
- **Unsaturated fats** are also associated with better cholesterol levels so are **preferable to saturated fats**. However because they are still high in calories too much should still be avoided.

SUGARY FOODS

Question: **What are examples of sugary foods?**
e.g. sweets, sugary drinks, iced cakes, jam, tinned fruit in syrup

- These can be **high in fat and calories** and can **put blood sugars up.**
- Your diet does not need to be sugar free but should be lower in sugar.
- If eating a sugary food try to eat only a small amount or a lower sugar option.

- Examples of lower sugar choices are: currant buns, scones, tinned fruit in natural juice, diet or low sugar drinks.

- Tell the group that while it may be simple to put individual foods into groups it can become more complicated when looking at a complete meal.

- Say you would like everyone to complete a brief exercise to look at the content of different meals.

Exercise 1 **(see exercise sheet 1 at end of the chapter) (10 minutes)**

Aim: *To ensure an understanding of food groups and how meals can contain several food groups.*

COFFEE BREAK (10 minutes)

2.7 HEALTHY EATING PRINCIPLES AND STRATEGIES (20 minutes)

Aim: *To revise healthy eating principles and establish strategies to follow these principles.*

- Brainstorm with participants the dietary rules that they have been told to follow.

- Summarise these rules then take each rule in turn and brainstorm strategies to help follow this rule.

- If inappropriate knowledge or beliefs are held challenge these. For example explain that it is not necessary to use diabetic foods as they offer no benefit and can be expensive.

- Ensure dietary discussions are appropriate for different cultures within the group

- Use probes and examples only when participants provide no examples.

Question: **What are the general dietary rules you have been advised to follow?**

Summarise:

- **Meals should be eaten at a regular time each day.**
- Your diet should be **based on starchy foods**.
- Aim for **at least 5 portions of fruit or vegetables per day**.
- Your diet should be **high in fibre**.
- Your diet should be **lower in sugary foods**.
- Your diet should be **lower in fats.**
- **Use unsaturated fats in preference to saturated fats**.
- Large portions of protein foods should be avoided.
- **Salt should be reduced** (this assists in control of blood pressure).
- **Recommended alcohol levels should not be exceeded** *(say you will talk more about these levels next week).*

Question: **What are the strategies you use to follow these principles**

Probe: **- How would you make sure your diet is high in starchy foods?**

e.g.
- eat more wholegrain bread/pasta/ basmati rice
- make these the main part of every meal

Probe: **- How can you make sure you eat at least 5 portions of fruit or vegetables per day**

e.g.
- eat fruit as a snack or a pudding
- try to eat at least 2 types of vegetable or a salad with your

main meal

- drink 1 small glass of fruit juice per day

Probe: **- How can you make sure your diet is high in fibre?**

e.g. - increase the amount of starchy foods and fruit and vegetables you eat

- choose wholegrain bread
- eat high fibre breakfast cereals e.g. shredded wheat, branflakes, porridge oats
- Eat more beans or lentils

Probe: **- How would you make your diet lower in sugary foods?**

e.g. - use artificial sweeteners (Sweetex, Canderel) rather than sugar

- choose diet or low sugar drinks instead of full sugar drinks
- cut down on eating sweets

Probe: **- How can you reduce the fat in your diet, especially saturated fat?**

e.g. - cut surplus fat off meat, or buy lean meat

- measure cooking oils with a tablespoon and use less
- skim oil off the surface of curries before serving
- use semi-skimmed or skimmed milk
- use low fat dressings
- cut down on pastry and pies
- eat less biscuits, choose lower fat options instead e.g. fruit

- **Explain that 95% fat free products may still be high in fat.**

Probe: **- Has anyone ideas about how to reduce the amount of protein in their diet?**

e.g. - have smaller portions of meat or fish

- avoid cheese or meat as snacks as these are both high in protein and fat
- eat beans or pulses instead of meat but not as well

Probe: **- What can you do to reduce the amount of salt in your diet?**

e.g. - eat less ready prepared meals as these are high in salt
– try flavouring foods with herbs or spices rather than salt
– do not add extra salt to your meal

- Tell the group that alcohol will be discussed next week

- Say that the strategies you have discussed can be applied to all meals whether you are cooking for yourself, eating in a restaurant, or buying a take-away.

2.8 GOAL SETTING (10 minutes)

Aim: *For each individual to set a suitable behavioural goal.*

- Say that the strategies that have been discussed can be used to help set dietary goals.

- Set your own dietary goal and tell the group what it will be.

- Ask each individual to select a dietary goal of their own or a goal for another behaviour if they would prefer. Assist individuals in defining goals.

- Goals should not be for weight loss, but for actual behaviours e.g. I will eat 2 pieces of fruit on 3 days of the week.

- For individuals who claim to already follow a healthy diet, encourage them to consider whether they eat enough fruit and vegetables, whether they eat too much of any food e.g. biscuits or whether there are particular situations where they have difficulty following their diet.

- Encourage individuals to be realistic and not over ambitious.

2.9 REINFORCEMENT (10 minutes)

Aim: *To discuss the use of rewards to reinforce behaviours*

- Introduce the idea of reinforcement using the reinforcement technique guide.
- Use brainstorming to think of suitable rewards, emphasise that food may not be the most suitable form of reward.
- Ask each participant to select a reward to give themselves if they complete their goal. Tell them to write this on their goal setting sheet.

Question: **Can you think of anything which could act as a reward?**

Probe: **- Is there a behaviour you could perform?**

e.g. Telephone a friend, Go out to a football match, save money from not buying cakes to buy magazine, flowers, video, lottery ticket

- Ask each individual to tell the group what their goal for the following week is and what reward they will give themselves if they achieve this.

2.10 SESSION CLOSE

- Tell participants that you will begin the session next week with feedback on goals.
- Say you will also be looking at i) some of the difficulties that can be experienced when trying to eat healthily, ii) how eating may be influenced by feelings and social situations and iii) how we can begin to deal with these difficult situations.
- Say you will also begin to look at the role of exercise in diabetes.
- Thank participants for coming.

Exercise 1

Materials

Set of food cards

Paper

Pens

White board/flip chart with food group headings (it may be useful to leave information gathered in section 2.6 in view.)

Split group into pairs, distribute 2/3 selected food cards to each pair (these can be selected to be most appropriate for specific pairs). Ask pairs to go through each card and identify which food groups are represented. Remind the group that how a food has been cooked might influence the food groups represented as well. Also ask groups to think about what the effect of the food/meal would be on their blood sugars.

Bring group back together and go through answers. Use to indicate that even a single food can fall into more than one group and the idea is to balance overall content of a meal.

It may be useful to draw a food plate to demonstrate the proportion of each food group that should be eaten.

N.B. Food cards will show a range of foods/meals including easier options e.g. meat, cheese and more complex meals e.g. lasagne, vegetable curry, meat pie as well as food from different cultures.

WHAT IS DIABETES?

With diabetes, your body is unable to control the amount of sugar (glucose) in your blood. Normally a hormone called insulin does this. In type 2 (non-insulin dependent) diabetes the insulin your body produces may be lacking or may not be working properly for you.

Some of the food and drink you take can affect your blood sugar, so you may need to change your diet. Diabetes cannot be cured, but it can be controlled by following a healthy diet. You may also need to take tablets or insulin.

Having good diabetic control is important to stop symptoms of diabetes and to keep you healthy.

WHY IS HEALTHY EATING IMPORTANT FOR DIABETES?

What you eat can influence:

1. your blood sugars
2. your blood pressure
3. your weight
4. your risk of heart (cardiovascular) disease and other complications

WHAT IS HEALTHY EATING FOR PEOPLE WITH DIABETES?

Healthy eating is the best way to keep your blood sugar level normal.

If you are overweight, losing weight will also help to improve your blood sugar control.

For good control of your diabetes follow these guidelines:

- Eat regular meals
- Eat starchy foods (carbohydrates) at each meal
- Eat more high fibre starchy foods (roughage)
- Eat at least five portions of fruit and vegetables each day
- Reduce your sugar intake by swapping high sugar foods for low sugar foods
- Use fats and oils sparingly. Only eat fried foods occasionally. Eat less fatty foods
- If you have kidney problems you may benefit from eating less protein
- If you have high blood pressure try to reduce the amount of salt in your diet.
- Watch your weight
- Don't drink more than the recommended amounts of alcohol

Special 'diabetic' foods are not necessary. They are expensive and will not help your diabetes.

STARCHY FOODS?

Eat some starchy food at every meal. Make it the main part of your meal.

Examples of starchy foods:

Bread, toast, rolls, pitta bread
Breakfast cereal, oat porridge
Potatoes - boiled or baked in skins (jacket)
Plaintain, yam, sweet potato, green banana, cassava, dasheen
Chapati, naan, roti
Rice, noodles, cornmeal, pasta e.g. spaghetti, macaroni
Beans/Pulses e.g. Baked beans, kidney beans, black-eye beans, lentils, chick peas

Some starchy foods are even better because they are more slowly absorbed by your body. These include:

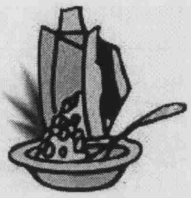
Pasta, wholegrain bread, basmati rice, green banana, yam, porridge oats.

HOW CAN I EAT MORE STARCHY FOODS?

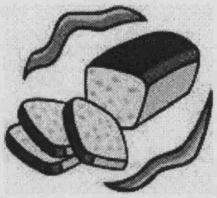
- ❑ eat more wholegrain bread, pasta or basmatic rice

- ❑ make these foods the main part of every meal

Looking at slowly absorbed starchy foods as better food choices



Whole grain cereals
All Bran or porridge



Multi-grain, rye and
pumpernickel bread

Pasta and Noodles

Beans, chick peas
and lentils

Green banana, yam
and sweet potato

Basmati and
easy cook rice

Starchy foods, such as bread, potatoes, pasta, rice and cereals, are broken down into glucose which is used to supply the energy needed for daily living.

The rate at which starchy foods are broken down into glucose depends on many factors such as how the food is prepared and cooked.

The **glycaemic index** (GI) ranks foods by how quickly they are broken down and how they effect blood glucose levels.

HIGH GI foods are broken down quickly and raise blood glucose levels quickly.

LOW GI foods are broken down slowly and raise blood glucose levels slowly.

Choosing lower GI foods such as those above may help you to:

- Improve your blood glucose control
- Lose weight
- Improve your cholesterol levels
- Reduce your risk of heart disease

Created by State Registered Dietitians, UCLH Trust, London. June 2002.

FIBRE?

Eat more high fibre foods.

Fibre or roughage is the indigestible part of fruit, vegetable and cereal products. There are two types of fibre, both of which are good for people with diabetes.

1. SOLUBLE FIBRE
   - this can help to control your blood sugar levels
   - this can help to lower the amounts of cholesterol in your blood

Foods rich in soluble fibre are: Vegetables, pulses (peas, beans and lentils), porridge oats, and fruit

2. INSOLUBLE FIBRE
   - This helps to fill you up and prevent constipation. This is particularly important if you are trying to lose weight.

Foods rich in insoluble fibre are: Wholemeal flour, high fibre breakfast cereals.

HOW CAN I EAT MORE FIBRE?

- ❑ Eat wholegrain bread rather than white
- ❑ Choose a high-fibre breakfast cereal e.g. Porridge Oats, Shredded Wheat, Branflakes, Weetabix
- ❑ Eat a wide variety of fruit and vegetables
- ❑ Include peas, beans and lentils in your cooking e.g. soups, stews, casseroles
- ❑ Boil or bake potatoes in their skins. Eat the skins

FRUIT AND VEGETABLES?

Try to eat at least 5 servings of fruit and vegetables each day.

These are an important source or soluble fibre. They also contain vitamins which may protect against heart disease.

You can eat any fruits or vegetables including: Fresh fruit, stewed fruit without sugar, tinned fruit in natural juices, all vegetables (potatoes, yams, plaintain are considered starchy foods).

- You should spread fruit out over the day. Don't have them all at once.
- One handful of grapes or one small glass of fruit juice is the same as a piece of fruit.
- Fruit juice (including unsweetened) contains a lot of natural sugar and is a common cause of high blood sugars. You should only drink one small glass a day.
- Dried fruit can be used as a sweetener for cereals or in baking, but you should not snack on this as it high in sugar.
- Eat tinned fruit in natural juices not syrup.

HOW CAN I EAT MORE FRUIT AND VEGETABLES?

- ❑ Eat fruit or raw vegetables as a snack or dessert
- ❑ Always eat at least 2 types of vegetable or a salad with your main meal
- ❑ Eat fruit as part of your breakfast

FATS?

Use fats and oils sparingly. Only eat fried foods occasionally. Eat less fatty foods

People with diabetes are more at risk of developing heart disease. Fats are also high in calories and are associated with weight gain. If you are overweight cutting down on fats is the quickest way to lose weight.

There are 3 main types of fat that you may have heard of.

1. SATURATED FATS
    - These mainly come from animals
    - They tend to be hard when cold
    - They are associated with the highest risk of heart disease

Foods containing saturated fat are: full fat milk, cheese, butter, fatty meat, poultry with skin on

2. UNSATURATED FATS
    - These tend to be liquid when cold
    - They are better than saturated fats but are still high in calories so need to be used in small amounts

Foods containing unsaturated fats are: olive or sunflower oils, oily fish, peanuts

3. CHOLESTEROL
    - This is a fat substance found in the blood
    - Raised cholesterol levels are associated with heart disease
    - Eating less fat, especially saturated fat will help decrease cholesterol levels.

HOW CAN I EAT LESS FATS?

FATS AND OILS

Cut down on frying	→	Grill, bake, casserole or steam, microwave
Use less butter/margarine/oil/ ghee	→	Use a low fat spread. Measure out oil using a spoon rather than just pouring into the pan

DRESSINGS

Use less mayonnaise, salad cream, sour cream, vegetable and olive oil.	→	Try low fat dressings, vinegar, lemon juice or natural yoghurt

MEATS

Avoid fat on meat. Use fewer meat products like sausages, pies and pasties	→	Choose a lean cut. Eat more dishes containing beans, pulses and fish and chicken.

MILKS AND YOGHURTS

Avoid full fat milks	→	Use semi-skimmed or skimmed milk
Use less Greek Yoghurt, cream, condensed or evaporated milk	→	Choose yoghurts or fromage frais that are low fat and have no added sugar i.e. diet or natural

CHEESE

Use less cheddar/hard/cream cheese	→	Try low fat cheeses - cottage cheese, half fat and reduced fat cheese.

SNACKS

Eat fewer crisps, peanuts, nuts, samosas, pakhoras and Bombay mix.	→	Choose fruit or raw vegetables instead.

SUGARY FOODS?

Reduce your sugar intake by swapping high sugar foods for low sugar foods.

You do not have to avoid sugar completely. It is only the foods and drinks that contain a lot of sugar that can cause your blood sugar to go too high. You should try to eat only a small amount of sugary foods, or choose a lower sugar option.

HOW CAN I EAT LESS SUGARY FOODS?

FOODS HIGH IN SUGAR		FOODS LOW IN SUGAR
Sugar,glucose, dextrose, sucrose.	→	Calorie free artificial sweeteners
Jam, marmalade, honey, syrup and treacle	→	Reduced sugar jams and marmalades or pure fruit spreads
Fruit squash. Cordials and fizzy drinks. Cream soda Lucozade, Lucozade light, Ribena light	→	Sugar free, low calorie, no added sugar and diet canned or bottled drinks and squashes. Tea, coffee, water
Sugary puddings	→	Have fruit or diet yoghurts. Use sugar-free packet dessert mixes or artificial sweeteners for home-made milk puddings
Sugar coated breakfast cereals	→	Use a high fibre cereal e.g. Porridge, Shredded Wheat, Branflakes, Weetabix
Sweets and chocolates. Indian sweets	→	Keep to small amounts for special occasions e.g. birthdays, weddings
Bought cakes, sweet pastries, sweet biscuits	→	Crumpets, teacakes, scones, plain biscuits Or Use half usual quantity of sugar when home baking. Keep to special occasions if overweight.
Milk shakes, condensed milk, energy drinks e.g. ISO Malt, Nutrament, Noursihment	→	Sugar free hot chocolate drinks, Cocoa.

PROTEIN?

If you have kidney problems you may benefit from reduced protein consumption.

Protein is used to repair damaged cells and in the growth of new cells.

High protein foods are: meat, fish, beans and pulses, lentils, eggs, cheese, milk

HOW CAN I REDUCE THE AMOUNT OF PROTEIN I EAT?

- ❑ Try to avoid peanuts or cheese as snacks as these are both high in protein and fat
- ❑ Cut down on the size of portions of meat or fish
- ❑ Eat beans or pulses instead of meat but not as well

SALT?

If you have high blood pressure try to reduce the amount of salt in your diet.

Eating less salt can help you keep your blood pressure under control, so you should aim to reduce the amount of salt in your diet.

HOW CAN I EAT LESS SALT?

- ❑ Eat fewer ready prepared meals and sauces as these tend to be high in salt
- ❑ Try flavouring foods with herbs or spices or lemon juice instead of salt
- ❑ Eat fewer foods preserved with salt e.g. bacon, olives, cheese, salami, ham
- ❑ Try to avoid flavouring foods with seasonings high in salt e.g. vegetable stock cubes, fried chicken seasoning etc.
- ❑ Don't add any extra salt to your meal

ALCOHOL?

The basic advice is not to exceed recommended limits:

- **2 units per day for women** (maximum per week 14)
- **3 units per day for men** (maximum per week 21)

- you should avoid drink alcohol on an empty stomach.

- If you take insulin and have been drinking you should take a starchy snack before going to sleep and should drink plenty of water.

- Liquor's or sherry are higher in sugar, try not to have more than one in a day.

- If you drink beer/lager keep to weaker strengths e.g. not Pils. Stronger beers are higher in alcohol and calories.

How many units of alcohol are there in my drink?

Alcoholic Drink	Units
1/2 pint Lager/Bitter	1 Unit
1 measure spirit (25ml)	1 Unit
1 glass wine 125ml (12%)	1.5 Units
1 bottle Becks (275ml)	1.4 Units
1 can Guinness (440ml)	1.9 Units
1 can Cider (440ml)	1.6 Units

SESSION THREE

Session Three - Objectives

By the end of the session each participant should:

- have identified both practical and emotional based difficulties of following a healthy eating plan
- be able to suggest strategies to overcome any practical or emotional barriers to healthy eating
- be able to select a suitable meal, including content and portion size, for both cooking at home and eating out
- have had the opportunity to role-play a situation where the social environment makes it difficult to follow a healthy eating plan
- be able to state what effect alcohol has on blood sugars
- be able to give examples of exercise that include both everyday activities and sports
- be able to give 6 reasons why exercise is beneficial
- have selected a strategy to deal with a personal barrier to exercise if appropriate
- have set a behavioural goal for the coming week

Session Three - Content

3.1 INTRODUCTION (2 minutes)

Aim: *To describe the main content of the session.*

- Tell the group that the session today has two main topics.
- I) Looking at some of the difficulties of following a healthy eating plan and how to overcome both practical and social barriers.
- II) The role of exercise in diabetes.

3.2 GOAL SETTING FEEDBACK (8 minutes)

Aim: *For each individual to speak within the group. To hear and reinforce the group's efforts with their goals.*

- Tell the group that firstly you would like to hear how people got on with their goals. Suggest you begin. Read your goal aloud and then mention problems or difficulties you had, pretending if necessary, to show that problems are acceptable.
- Ask each participant to provide feedback on their goal from last week using the question below. Emphasise that it is important to mention difficulties as well as successes.
- Ask if individuals found rewards useful.
- Thank each participant for their response. Reinforce each individual for their effort, regardless of outcome.
- If an individual mentions a non-dietary problem define what the problem is,

then with the group examine different strategies to deal with the problem. Ask individuals to select a strategy they could try.

- If an individual mentions a problem related to healthy eating write the problem on the flip-chart. Tell the group that you will discuss ways to deal with these problems once everyone has given feedback on their goals.

Question: **Let's go around the group and can each person remind us what goal they set to do and tell us how they got on. Say what you managed and whether you had any problems. Can you also tell us whether you found your rewards useful.**

3.3 BARRIERS TO HEALTHY EATING (15 minutes)

Aim: *To discuss problems or situations where it is difficult to follow dietary advice. For patients to recognise that practical situations, moods, thought processes and social situations influence eating behaviour.*

- Say that some problems with following a diet have already been mentioned (during goal feedback). Say that you would now like to look in more detail at these types of problem.

- Use the question below to brainstorm as many different problems or barriers to healthy eating as possible. Ensure that practical problems and social or emotional problems are written on separate sheets, so that they can be discussed independently.

- Use probes and the examples provided if necessary.

Question: **Can you think of any difficulties you have with following your diet or situations that make it more difficult?**

Probe: **- Are there any ways that you feel, or certain moods that you have that influence how you eat?**

- Do you ever eat differently when you are very busy or under stress?

- Can you think of anything which would make it difficult for other people to eat healthily?

- Does anyone ever find ...(use example)

Example Problems:

- Food does not taste as nice when cooked without salt (practical)
- It is easier to buy ready meals when busy (practical)
- I tend to eat for reasons other than hunger e.g. boredom, feeling low, habit (mood)
- Eating rich food is a sign of prosperity in my culture (belief)
- It is difficult to cook healthy meals because I do not feel they are what my family want to eat (social)
- Friends pressurise me to eat (social)

3.4 DEALING WITH PRACTICAL DIETARY PROBLEMS (10 minutes)

- Indicate from the brainstorming sheets that some of the problems with following a diet are practical.
- Tell the group that you would like to work through each problem and see if there are any things that could be done to overcome these problems.
- Use probes and examples if necessary.

Probe: **- Are there any things that you do that make it easier for you to follow your eating plan?**

Example Problem	Possible strategy
Food does not taste as nice when cooked without salt	- experiment with spices - slowly reduce the amount used
I do not have enough information	- go to a library, see a dietician
Healthy food is too expensive to buy for one person	- try buying and cooking in larger quantities and freezing meals

- Tell the group that one of the most difficult practical problems is knowing what to eat and how much. Suggest this can be particularly difficult when eating out or getting a take-away.

- Tell the group that you are going to do a practical exercise to look at selecting appropriate meals both for content and size.

- Explain exercise one.

Exercise 1: **(see exercise sheet 1 at end of chapter) (15 minutes)**

3.5 DEALING WITH EMOTIONAL OR SOCIAL DIETARY PROBLEMS (15-20 minutes)

- Return to brainstorming sheets and point out that problems with following a diet may also be the result of how we feel, or the social situation one is in.

- Tell the group that you would like to work through each problem and see if there are any things that could be done to overcome these problems.

- Use probes and examples if necessary.

Probe: **- Has anyone tried anything which has made it easier to cope with these situations?**
- If a friend came to you with this problem what would you suggest they did?

Example Problem	Possible strategy
I tend to eat for reasons other than hunger e.g. boredom, feeling low or habit	- think of other things to do e.g. read, call a friend, go for a walk - eat something healthier e.g. apple
It is difficult to cook healthy meals because I don't feel they are what my family want to eat	- discuss diet and ways you can overcome the problem with your family

Friends pressurise me to eat	- tell friends you have diabetes, ask them not to pressure you

- Explain that one of the most difficult problems can be when you are not cooking or selecting foods, maybe because someone else cooks in the family or you are eating at a friend's house or at a restaurant. Also, it can be difficult to say no when people pressurise you.
- Suggest that it can feel as though you have no control over what you are eating.
- Explain that it is important to learn that you still do have control, but it may require negotiations with another individual.
- Say that you will learn how to do this in the next exercise

Exercise 2 **Refer to exercise sheet 2- role-playing at end of chapter (10 minutes)**

- Finish role-plays and say that while these techniques will be useful in many social situations that on **occasional** major celebrations, e.g. Christmas, Diwali, it is OK to treat yourself, providing this does not become a regular event.

3.6 ALCOHOL AND DIABETES (5 minutes)

Aim: *To cover the informational content on appropriate use of alcohol in diabetes.*

- Say that one other important aspect of diet is alcohol. Discuss the information below.

Question: **Does anyone know what the advice for people with diabetes is about drinking alcohol?**

Probe: **- Are there any drinks that you think are better or worse if you have diabetes?**

Summarise:

- The basic advice is not to exceed recommended limits:
- **2 units per day for women** (maximum per week 14)
- **3 units per day for men** (maximum per week 21)

- Show overhead 3.1, emphasise that these are often higher than many people think e.g. wine and bottled beer

Overhead 3.1

- It is **best to have 2 or 3 completely alcohol free days** each week.
- You should **avoid drinking alcohol on an empty stomach**.
- **If you take insulin and have been drinking you should take a starchy snack before going to sleep** and should drink plenty of water.
- Some liquors and sherry can be sweet. You should only drink these in small quantities or replace them with dryer options e.g. dry sherry.
- If you drink beer or lager keep to weaker strengths e.g. not Pils. Stronger beers are higher in alcohol and calories.

- Tell the group that after coffee you will move on to look at exercise.
- Suggest that everyone looks at their previous goals. Ask if anyone wants to update their goals or make another goal to take into account strategies to deal with problems. Model an updated goal yourself.
- Distribute the goal setting sheets and help individuals goal set appropriately.
- If someone wants to stick with their goal from last week because they did not succeed or found it difficult this should be allowed.

COFFEE BREAK (10 minutes)

3.7 EXERCISE AND DIABETES – INTRODUCTION

Aim: *To emphasise that exercise includes everyday activities as well as sports.*

- Tell the group that for the rest of the session you will be looking at exercise.
- Say that you know that this is a behaviour which both people with diabetes and those without often find difficult. Therefore you are going to be looking at what motivates people to exercise this week. Say that next week you will look more closely at how to exercise.
- Suggest that you begin by thinking about what is meant by exercise. Use the question to hold a brainstorm session. The examples provided should only be used if the participants have no ideas.
- Throughout the discussion on exercise you may meet negative beliefs and resistance. The group may be a useful way of challenging such beliefs, however any disability of cardiovascular limitations of individuals should be kept in mind.

Question: **Let's list all the activities you think of when you think about exercise.**

Probe: **- Are there any more day to day activities you could consider as exercise**

- **Does exercise have to make you out of breath? Are there other types of exercises?**

Examples:

	Increase Heart Rate	Improve Strength
Everyday Activities	Brisk Walking Stair-Climbing Line Dancing Gardening	Carrying Heavy Shopping Gardening D.I.Y.
Sports	Swimming, Golf Cycling, Aerobics	Weight Training

- Try to elicit both sports and everyday activities. Also include some activities which will improve strength as well as increase heart rate.

- The aim is to name enough different activities so that even the most sedentary person in the room may feel that they could become more active.

Summarise:

- There are **numerous everyday activities that can be considered as exercise** if they are done in the right way.

- This means **everybody should be able to find some activity** which they are both capable of and would enjoy doing.

- Exercise falls into two broad categories
  i) Exercise which **increases your heart rate and improves your cardiac health**
  ii) Exercise which **increases strength**

- In this programme we are going to concentrate mainly on the first type of exercise, i.e. exercise which increases your heart rate.

- This means exercise where you become slightly out of breath. For example walking is a good exercise but needs to be more than an amble around the shops, you should get a little out of puff.

3.8 BENEFITS OF EXERCISE

Aim: *For the group to realise that they would gain benefits from exercising.*

- Tell the group that before we can motivate ourselves to do exercise, we need to think about why exercise may be beneficial.

- Review the benefits of exercise using the question and probes, then summarise.

Question: **What benefits have you ever experienced, or been told you would experience from exercise?**

Probe:
- **Do you know of any benefits exercise has on your blood sugars?**
- **Have you experienced any changes in your mood after exercise?**
- **How do you feel after you have exercised?**
- **What effects does exercise have on your body in the long-term?**

Summarise:

- **Exercise can improve blood sugar control.**
- **Exercise can help your heart and lungs work more efficiently.** People with diabetes who exercise are 30-50% less likely to get heart disease than people with diabetes who do not exercise.
- **Exercise can help you lose weight and look better.** Combining exercise and a weight loss diet can be more effective than diet alone.
- **Exercise can help lower your blood pressure.**
- **Exercise can help you feel better mentally and emotionally.** It reduces both stress, anxiety and depression and can help you feel more positive.
- **Exercise can reduce pain and stiffness.** It can help to keep you independent and mobile.
- **Exercise can be good for other health problems** e.g. arthritis. Providing the right exercises are selected, and completed at the correct pace, most conditions can benefit from exercise.

3.9 BARRIERS TO EXERCISE

Aim: *To discuss problems or situations that act as barriers to exercising. Also, to identify situations or factors that can make it easier to exercise*

- Explain that even if we know exercise is good, it can be another thing to actually get started.
- Suggest that it will be useful to look at the reasons why we do not exercise and what makes it more difficult to exercise (Brainstorm).
- As with diet probe for practical, emotional and social barriers.

Question: **Why might you not exercise or sometimes find it more difficult than at other times?**

Probe: **- Are there any worries you have that make you less likely to exercise?**
- Are there things that other people say or do which make you avoid exercise?
- Are there situations where you do not exercise?

Example Barriers:
- I do not have time to exercise (practical)
- I can not afford to exercise (practical)
- I do not exercise when I feel low (mood)
- I feel silly exercising, I feel self-conscious (feeling)
- I am too old (feeling)
- It is too boring (feeling)
- I am afraid of having a hypo (feeling)
- Other people would laugh if I said I was going to exercise (social)

Question: **Now can we list any reasons that make it easier or more likely you would do exercise?**

Examples

- I find it easier when I have planned exactly when and what I am going to do to exercise
- It helps when I do an exercise I enjoy
- It is good if I know everyone else feels as silly as I do
- If I have told a friend that we will go together, I feel bad if I let them down
- I always feel good afterwards, so if I hold onto that thought it makes it easier
- I promise myself a treat if I do it
- It is easier to exercise when I am with someone who knows what to do if I feel ill

- Use Exercise 3 as a method of dealing with barriers to exercise.

- The table below presents example problems and probes for solutions. These should only be used if the group has difficulties.

Exercise 3 Have each group member think of two problems related to exercising. Suggest that it is preferable if the examples are personal but that they do not have to be. Start with one person stating a problem. Ask the group to generate strategies that could be used to help with the problem. If the problem is something the individual experiences ask if they would like to select a strategy to use when they next experience this problem. Move on to the next person and repeat. If their problem is the same as the one selected previously suggest that they choose another problem, come back to them if necessary.

Point out that some people may exercise successfully already. Ask them to think about the future and whether there would be any situations that could threaten their current behaviour. How would they deal with this situation?

Problem	**Probe**
I do not have time to exercise	Make a specific plan of when in your day to exercise
I find exercising lonely	Find a friend or partner to walk with etc

I can not afford to exercise	Choose an exercise which is free, e.g. walking, increase general activities like stair climbing
I do not exercise when I feel low	Set yourself a reward that will cheer you up if you do exercise. It is likely that just exercising will make you feel better
I feel silly exercising, I feel self-conscious	Get a stationary bike so you can exercise on your own, or choose classes with other beginners.
I am too old	No-one is too old, increasing things like stair-climbing is still exercise
Exercise is too boring	Choose an activity you like
I am scared of having a hypo	Make sure you go out with someone who understands what to do if you become ill

- Tell the group that the aim of looking for strategies around problems is to see that barriers to exercise can be overcome, and that increased exercise or activity level is possible for everyone.

- Say that you will discuss exercise more next week, but before then you would like people to think about how they could become more active.

3.10 SESSION CLOSE

- Remind the group that everyone has set a new goal. Ask each individual to remind the group what their goal is for the coming week.

- Tell participants that you will begin the next session with feedback on goals.

- Say that you will then be looking at how to do exercise safely.

- Say that you will also begin to look at the role of medication in diabetes.

- Thank participants for coming.

Exercise 1

Material Required

Food Models

Take-away/ Restaurant Menus

Split the group into pairs. The facilitator should select which individuals work together and where possible should aim to put individuals with similar eating issues together. For example overweight individuals where portion size may be an issue should be put together. Individuals where weight loss is not an issue should be together etc.

Each pair should be asked to design a meal including main course and dessert. Each pair will be asked to design two situations

i) cooking your own meal – use food models

ii) eating away from home – pairs given choice of take-away or restaurant menus.

The task is to design a healthy meal in each situation and to be able to identify the dietary principles that are being applied in making the decisions.

Emphasise that when designing the meals they should consider portion sizes.

Give participants approximately 10 minutes to design both meals. During this period the facilitator can observe participants and help teach appropriate portion sizes and content, this should however be in the context of correcting mistakes rather than guiding selection. After 10 minutes the group should be brought together and each pair should report back on one of their situations (facilitator directed). The facilitator should emphasise which parts of the selection are good and anything that may be less suitable. Reinforce all participants for their efforts.

Variation on exercise:

An alternative form of this exercise is to ask participants to illustrate a meal they would normally eat at home then the facilitator can work through with group how this might be improved.

If time is limited it may be appropriate for half the group to use food models and the other half food menus. Feedback should however, be with the whole group.

Exercise 2 – Role Plays

Materials Needed

None

Tell participants that making requests from other people whether at a restaurant or with friends or family can feel daunting. However, if done successfully it will enable them to remain in control of their diabetes, allow them to enjoy social situations more, and make following their diet easier.

Say that when requests are made of other people it is important to:

i) be clear in what you are asking for

ii) explain why you are making the request

Tell the group you are going to role-play three situations to give them the idea. Examples are given below but facilitators should feel free to devise their own situations. Role-play those situations you feel most suitable for the specific group. Split participants into pairs and tell them they can choose to role-play any sort of eating out or interaction with a friend. Reassure them there are no rights or wrongs it is just to practice and that the pairs will swap roles. Spend a little time with each pair making any suggestions of how they could improve what they say.

N.B. The situations most suited to the specific group can be chosen.

Example 1

Situation - English restaurant

Waiter:	Are you ready to order?
Person with Diabetes:	Could I ask you a couple of questions about the menu?
Waiter:	Of course
Person with Diabetes:	Would it be possible to have the sauce served separately from the meat?
Waiter:	Well usually it is served together

Person with Diabetes:	Yes I understand that but I need to follow a low fat diet so I would prefer to be able to add it myself, could you ask the chef if this is possible
Waiter:	Yes I will see what he says
Waiter:	I'm afraid it is not possible to do that
Person with Diabetes:	OK then could you suggest something that has been grilled, something that is low in fat
Waiter:	You could try the fish
Person with Diabetes:	Fine I'll have that then

Example 2

Situation - Café

Waitress:	Can I take your order
Person with Diabetes:	I'd like the English breakfast but can you tell me do you grill or fry your bacon and sausages?
Waitress:	We fry them
Person with Diabetes:	Is it possible to grill them for me
Waitress:	Well we don't normally do that
Person with Diabetes:	Well you see I have diabetes and need to follow a low-fat diet. Could you ask the cook if it's possible. Also I'd prefer a poached egg rather than fried.
Waitress:	OK I'll ask... he says that's fine

Example 3:

Situation - Being asked to dinner by a friend

Friend:	Hi, John would you like to come over for dinner next week?
Person with Diabetes:	Yes, that would be lovely. Actually maybe its worth me mentioning that with my diabetes I have to be a bit careful with what I eat.
Friend:	Well what is it that's not suitable
Person with Diabetes:	Well really I'm meant to stick to a low fat diet, also anything that's high in sugar is a bit of a no no.

Friend: Oh that's fine, I can easily cook round that

Person with Diabetes: I hope you don't mind me mentioning it

Friend: No of course not, it makes it easier than me cooking the wrong food

Person with Diabetes: Thanks, I'll see you next week then.

Example 4:

Situation - At friends house with food that is high in fat,

Person with Diabetes: Could I have just a little of the chicken curry please

Friend: Why, don't you like chicken

Person with Diabetes: No its not that, you know its with my diabetes I need to be a bit careful. The vegetables look lovely though so maybe I could have a few more of those

Friend: I'm sorry I didn't know. I wish I had done something else

Person with Diabetes: No, honestly this is fine, I can have most things just as long as its not too much.

Friend: Oh that's good, and at least I'll know for next time.

Example 5:

Situation – friends pressurising you to eat a cake

Friend: Shall I buy a piece of cake for you Hilda?

Person with Diabetes: No I don't want some thank you

Friend: Oh go on we're all having some, I know you want some

Person with Diabetes: Thank you for your thought but I really don't want any. It will make my blood sugars too high and I don't want to make myself ill

Friend: Oh surely it won't matter that much

Person with Diabetes: No honestly I'd rather not

Friend: Not even just a small piece

Person with Diabetes: No, I'd rather not.

Friend: Well ok but I'm going to have some just have a bite of mine.

Person with Diabetes: OK then I'll just have a mouthful to try it.

Overhead 3.1

Alcohol and Diabetes

Alcoholic Drink	Units
1/2 pint Lager/Bitter	1 Unit
1 measure spirit (25ml)	1 Unit
1 glass wine 125ml (12%)	1.5 Units
1 bottle Becks (275ml)	1.4 Units
1 can Guinness (440ml)	1.9 Units
1 can Cider (440ml)	1.6 Units

SESSION FOUR

Session Four - Objectives

By the end of the session each participant should:

- be able to name two ways of rating whether they are exercising at the right level
- be able to list two symptoms that indicate exercise is at an appropriate level, and two symptoms which indicate exercise is too hard
- be able to describe appropriate foot wear and foot care in relation to exercise
- be able to define hypoglycaemia and how it should be treated
- be able to state what to do if side-effects of medication are experienced
- have practised injecting insulin if desired
- be able to explain how to deal with sick days
- have set a goal for a behaviour of their choice.

Session Four - Content

4.1 INTRODUCTION (2 minutes)

Aim: *To describe the main content of the session*

- Tell the group that the session today has two main topics.
- I) You will be looking at how to exercise safely and enjoyably.
- II) You will begin to look at the role of medication in diabetes.
- Say firstly you would like to hear how people got on with last weeks goal.

4.2 GOAL-SETTING FEEDBACK (8 minutes)

Aim: *For each individual to speak within the group. To hear and reinforce the group's efforts with last weeks goals.*

- Tell the group that firstly you want to hear how people got on with their goals. Suggest you begin. Read your goal aloud and then mention problems or difficulties you had, pretending if necessary, to show that problems are acceptable.
- Ask each participant to provide feedback on their goal from last week using the question below. Emphasise that it is important to mention difficulties as well as successes.
- Thank each participant for their response. Reinforce each individual for their effort, regardless of outcome.
- If an individual mentions a problem define what the problem is, then with the group examine different strategies to deal with the problem. Ask individuals to select a strategy they could try. Where appropriate challenge negative or false beliefs.

Question: **Let's go around the group and can each person remind us what they contracted to do and tell us how they got on. Say what you managed and whether you had any problems. Also, can you tell us whether you found your rewards useful.**

4.3 WHAT IS A SUITABLE LEVEL OF EXERCISE (10 minutes)

Aim: *For the group to understand how hard they should work when they exercise.*

- Move on to a discussion about how to exercise safely.
- Begin by looking at the ideal amount and intensity of exercise using overhead 4.1.
- Emphasise that individuals need to work at their own pace and build up exercise slowly.
- If any individual has a disability or heart disease be careful to emphasise the importance of discussing exercise with their doctor before they begin.

Question: **Does anyone know how much exercise they should be doing a week?**

Summarise:

- As we saw last week **everyone is at different levels** with the amount they exercise.
- It can be **useful to know what is the ideal level** for our health to benefit.
- This is generally **around 30 minutes, 3-5 times a week**. This should be thought of as a target to build up to, not necessarily something to aim for straight away.

- If you do not do any exercise right now it would be an achievement to walk for 10 minutes every other day to start with.

- We also **need to know how hard to work**.

- Ask question and then use overhead 4.1 to summarise how hard exercise should be.

Question: **Does anyone know how to tell whether they are exercising hard enough?**

Summarise:

- **If you rate how hard you feel you are exercising on a scale of 1-10 you should aim for 3-5.** Above this is too hard, below is too easy.

- Another way is to **measure your heart rate**. To do this, take your pulse for 15 seconds and multiply it by 4. The level you should aim for depends on your age which can be seen on table two.

- A third method, and probably the easiest, is to **think about the symptoms you feel when you are exercising.**

- Brainstorm the symptoms associated with exercise. When writing these on the flip-chart keep those symptoms which should be felt separate from those which should not.

- Use overhead or flip-chart to summarise symptoms that should and should not be felt.

Question: **What are the physical sensations you associate with exercise?**

Probe: **- If you have to run for the bus what do you feel like afterwards?**

4.4 MAKING EXERCISE SAFE (5 minutes)

Aim: *To ensure individuals know the necessary precautions to avoid the risk of injury during exercise.*

Question: **Are there any precautions or actions you think you should take to make sure exercise is safe?**

Summarise:

- Exercise should start and finish with easier periods called **warm-up and cool down periods.**

- These can just be doing the **same activity but a bit slower** e.g. walking casually for five minutes (warm-up) walking a bit faster for the next 10 minutes (exercise), finally walking slowly again for five minutes (cool down).

- The reason we do this is to **prepare the body and stop muscles aching after exercise.**

- Tell the group that there are a few other guidelines for making exercise safer and more enjoyable, but first you want to think about the kind of exercises people will be doing.

- Remind the group that last week you asked them to think of an exercise or activity they might like to try. Ask question.

- For those people who already exercise tell them to say what they do currently.

- Indicate that most exercise involves being on your feet. Ask group what precautions should be taken for their feet during exercise.

Question: **Can everyone tell us of an exercise that they would like to try, or an activity that they could do more of?**

Probe: **- Why might this be?**

- Because diabetes can affect the feet, it is very important to **make sure footwear is suitable** at all times, but especially during exercise.

- The most important thing is for shoes to be **comfortable and secure.**

- Trainers or soft lace-up or velcro shoes are ideal. Slip on shoes may rub if any distance is walked in them.

- It is **important to make sure that shoes fit well**. If you have an old pair of trainers make sure that they still fit.

- Feet can change shape with diabetes e.g. the toes may claw up, so it should not be assumed that old shoes will still fit.

- Also some people have less sensation in their feet with diabetes.

- This means that **feet need to be checked feet for cuts and blisters after exercise.**

- Feet should be gently washed and dried after exercise. Moisturiser may be put on the heels but not between the toes.

- Highlight to the group that if on insulin exercise can cause hypoglycamia.

- Indicate that you will discuss the relationship of exercise and hypoglycaemia later on when looking at medication.

4.5 GOAL SETTING (10 minutes)

Aim: *Set goal for exercise or other behaviour*

- Model goal setting for exercise by setting your own exercise goal for the coming week. Read this aloud to the group.

- Assist individuals in setting short-term goals for either exercise or a behaviour of their choice.

- If an exercise goal is selected emphasise that any increase in activity is a legitimate goal providing it is well defined.

- It is very important to set the goal at an achievable level. If useful use overhead 4.3 to help individuals think about their current exercise level.

- Individuals who have no intention of increasing activity could be encouraged to make a list of the pros & cons of exercise as their first goal.

- Individuals who already exercise may want to think about a time when they expect to face barriers to exercise. Probe whether they exercise even when it is raining. What could they do in these situations?

- Ensure everyone has a reward they will receive at set points during goal.

COFFEE BREAK (10 minutes)

4.6 MEDICATION AND DIABETES (15 minutes)

Aim: *To discuss the function and characteristics of diabetes and blood pressure medications.*

- Tell the group that you would now like to talk about medications and diabetes.
- Explain why medication is important in diabetes.
- Ask each person to tell the group whether they take any medication for diabetes.

Information:

- Although diet and exercise play an important role in controlling blood sugar this often needs to be supplemented by medication.
- **Diabetes medication is either tablets or insulin**.
- These **help control blood sugars** so that the risk of complications can be reduced.
- **Increasingly, people with diabetes take tablets for blood pressure.**
- This is because they have also been shown to reduce the risk of long-term complications.

Question: **Can everyone tell us whether you are on medication for your diabetes and blood pressure, and if so what it is. If you can not remember the names just tell us if you take tablets or insulin.**

- Record medications on flip-chart according to mechanism (do not write headings).
- For blood pressure medications just list to illustrate how many different tablets there are. It is not necessary to categorise them.

Blood Glucose Medication

↑ insulin secretion	↓ insulin resistance	↓ rate of digestion of carbohydrates	Insulin
-Sulphonylureas: gliclazide tolbutamide glibenclamide chlorpropamide -Repaglinide	-Metformin -Glitazones: rosiglitazone	Acarbose	

- Say that to understand how these tablets work it is useful to think about what is happening in diabetes.

- Ask the question then summarise the action of each group of drugs (not necessary for blood pressure tablets).

Question: **Can anyone tell us how these tablets work?**

Summarise:

- Tablets in the first column stimulate the production of more insulin.

- Tablets in the second column make the body more sensitive to insulin.

- Drugs in the third column act by delaying the digestion of starchy carbohydrates.

- Insulin provides the body with extra insulin.

- Explore how individuals feel about increasing medication by asking question and use to explain the relationship of increasing medication and seriousness of diabetes.

Question: **How do you feel if the doctor tells you that you need to increase your tablets, or maybe go onto insulin?**

Probe: **- What does this make you think is happening with your diabetes?**

Summarise:

- People can think an increase in medication implies their diabetes is getting more serious.

- The pancreas does produce less insulin over time and in this way **diabetes is progressive,** however it **is the risk of complications that is the most serious aspect of diabetes**.

- **Controlling blood sugars will reduce the risk of complications.**

- Therefore, the **amount of medication or insulin** taken **to achieve good blood sugar control** and reduce complications **is not an indicator of seriousness.**

- The **same is true for blood pressure**, it is not the number of tablets taken that is important, but the fact that levels are controlled.

4.7 SIDE-EFFECTS AND MEDICATION (5 minutes)

Aim: *To cover any side effects that people experience and emphasise the importance of discussing these with the doctor rather than just stop taking medication.*

- Elicit side effects from patients and advise them how to avoid these. It is not necessary to address side effects not experienced by the group.

- Emphasise the importance of discussing these with the doctor rather than just stopping taking medication.

Question: **It can be useful to know if anyone has experienced any side-effects with their medications? Has anyone here experienced side-effects with their diabetes medication or blood pressure tablets?**

Probe **- Does anyone experience any side-effects with their water tablets?**

Summarise:

- **Metformin** can be associated with flatulence and diarrhoea. This can be helped by taking tablets just after meals.

- **Sulphonylureas** can increase appetite and weight gain and may cause hypoglycemia. These should be taken 20-30 minutes before a meal so that insulin reaches the blood at the same time as your food.

- **Acarbose** can be associated with flatulence and diarrhoea. This can be helped by your doctor starting you on a low dose and increasing the levels very slowly (every 1-2 weeks).

- **Insulin** – this can cause people to put on weight. Careful monitoring of what you eat when you start insulin or changing onto a different insulin may help this.

- **ACE inhibitors** can cause a dry cough
- **Various blood pressure tablets** can cause impotence
- **Calcium Channel blockers** can cause ankle swelling

- Tell the group that if someone experiences side-effects it can reduce their quality of life and they may be tempted not to take the tablets as they have been advised. Ask if anyone has ever done this.

Question: **Does anyone ever skip taking their tablets because of side-effects? What could you do instead of missing tablets?**

- Advise the group that it is always best to discuss side-effects with the doctor, rather than not taking the tablets or suffering unnecessarily.

- Say that some people find it difficult to raise or explain problems with the doctor. Suggest there are things that they can do which will make this easier. Ask if anyone has any ideas and then summarise the information.

Question: What can you do to make speaking to the doctor easier?

Summarise:

- When speaking to the doctor it is important to **be as clear as possible** about the problems you experience.

- It may help to **make a note of exactly when and in what context the medication causes you problems.**

- Take the note to the consultation to remind you of what you need to tell the doctor.

- **Try practising what you need to say to the doctor before you go**. This will make it easier when you have your appointment.

- Remember **you and your doctor should work as partners**, you are both experts.

- Try to **work with the doctor to find solutions** to problems rather than expect the doctor to solve problems for you.

4.8 INSULIN AND DIABETES (30 minutes)

Aim: *To discuss and dispel some of the fears around taking insulin. To demonstrate how to give insulin injections.*

- Explain that although not everyone is on insulin it is increasingly being used to treat people with type 2 diabetes.
- Say that many people have worries and concerns about going onto insulin.
- Say that you would like to discuss these worries and concerns and whether they have changed for people already on insulin.
- Brainstorm and discuss the groups feelings about going onto insulin and whether people on insulin still find it a problem.
- The table shows example concerns and responses that may be raised. The aim is for those people taking insulin to reassure those who are not yet taking insulin.

Question: **For those people not on insulin how would you feel if you were told you needed to start taking insulin?**

Probe: **- What would you be worried or concerned about?**
- Did people who are now on insulin have these concerns before going on to insulin?
- Did anyone have other concerns?
- Do people who are now on insulin find these concerns were valid?

Concern	**Reassurance (preferable if this is from group)**
I am afraid of needles/pain/ practicality of injecting	- The needles used are very fine and injecting is often less painful than HBGM -mention practical

It feels like a life sentence	- It will become a habit and will allow you to live more fully. - It can be tried for 3 months initially
I feel like I have failed at my control	- emphasise that serious means getting complications not changing medication
Insulin will make me gain weight	- this can be controlled by watching what you eat initially or trying another insulin
I will be tied to a very strict eating regimen	- your doctor should be able to select a regimen that is suitable for you
I may lose my job if people know I take insulin	- this may apply if using machinery but there may be ability to move to a desk job.
I may become addicted	- you could survive without insulin but your blood sugars will not be well controlled which will increase the risk of complications.

- Say that one of the biggest worries is about the practicalities of injecting.
- Tell the group that you are going to do a practical session to reassure people who do not inject that it is not difficult, and to revise good practice for those who do.
- Perform practical, cover information.

Practical **How to Inject Insulin (15minutes)**

Step 1 – Facilitator demonstration

i) show group different devices

ii) explain that injections are into fat and not muscle

iii) demonstrate on oneself (the aim here is to demystify the process)

Step 2 – Patient practice

i) ask if anyone wants to practice or revise giving insulin

ii) help each individual insert the needle

iii) if any of the group are taking insulin revise the idea that injection sites need to be rotated

iv) reinforce individuals for successful injecting

Question **Does anyone know how often people on insulin need to take injections?**

Summarise

- There are **two common patterns** to injections:
- I) **insulin at night, tablets during the day**
- II) **insulin twice daily** half an hour before breakfast and evening meal
- This allows insulin to be absorbed before food is eaten.
- Your doctor or nurse will select the best regimen and dose with you.
- This regimen may vary over time to ensure you get the best control possible.
- For this reason different **people may need different amounts of insulin.** Remember insulin, like any other hormone in the body, is a natural substance. Different individuals need different levels of insulin to function at their best.

Question: **Can anyone remind us what hypoglycaemia is?**
Probe: **- What can make this more likely to occur?**

- Remind group that blood sugar levels below 4.0 indicate hypoglycaemia. This should be treated immediately by eating or drinking something which is sweet and can be absorbed quickly e.g. fruit juice or taking 3 dextrose/sugar tablets.

- This is more likely when taking insulin if i) you have taken too much insulin, ii) you have not eaten enough food, iii) you have recently exercised.

- Hypoglycaemia is one reason blood testing needs to be more frequent.

- If you feel 'low' you should test your blood sugar.

- **If exercising, test your blood sugars before and after exercise** and respond to the levels if low by taking a snack.

- The best foods to eat before exercise are starchy carbohydrates e.g. bananas. This will help to avoid hypoglycaemia.

- **Carry glucose tablets** while you exercise so hypoglycaemia can be treated immediately if you suddenly feel your blood sugars are low.

- If blood sugars indicate hypoglycaemia after exercise this should be treated by eating or drinking something which is sweet and can be absorbed quickly e.g. fruit juice or taking 3 dextrose/sugar tablets.

4.9 SICK DAYS AND MEDICATION (5 minutes)

- Tell the group that one final thing that you would like to discuss while talking about medications is what to do if they are sick. Ask question.

Question: **Does anyone know what they should do if they are sick and can not eat as normal?**

Summarise:

- Often people think it is best not to take insulin or tablets if they are sick and not eating.

- This is wrong **you should still take your medication when ill.**

- You should **check your blood sugar before each meal time**.

- **Normally it will be higher than usual**, this is because the illness itself can make your blood sugar rise.

- If blood sugars are in single figures and you cannot eat solid food you should **take small but frequent sips of orange juice** as this will prevent your sugars falling too low.

- Tell the group that next week you will talk more about medications and whether there are situations when people forget or choose to take medications differently from what they have been prescribed by their doctor.

4.10 SESSION CLOSE

- Remind group that everyone has set a new goal. Ask each individual to remind the group what their goal is for the coming week.

- Tell participants that you will begin the next session with feedback on goals.

- You will then look a little more at medications and how it feels to take tablets or insulin

- Say that as it is the last week you will also finish by bringing everything together and looking at how behaviours interact, both with each other and with the life that you want to live.

- Thank participants for coming.

Overhead 4.1

BECOMING MORE ACTIVE

Ideal Level of Exercise

Duration: 20-60 minutes
How Often: 3-5 times per week
How Hard: Moderate to Strong (Perceived Exertion Rate)

Table one

Number	How Does it Feel?
0	Nothing at all
1	Very Weak
2	Weak
3	Moderate
4	Somewhat Strong
5	Strong
6	
7	Very Strong
8	
9	
10	Very, Very Strong

Table Two

60-80% of Maximum Heart Rate

Age Range	Pulse Rate when Exercising
30-40	112 - 144
40-50	104 - 136
50-60	96 - 128
60-70	88 - 120
70- 80	80 - 112
80+	72 - 96

Overhead 4.2

What Should I Feel?

Warm, slightly sweating

Slightly Increased Heart Rate

Increase in Breathing Rate

Able to Talk

Comfortable

What Shouldn't I Feel?

Dizzy

Nauseous

Difficulty Breathing

Unable to Talk

Pain

Exhausted

Overhead 4.3

CURRENT ACTIVITY LEVEL

LEVEL	WHAT I DO NOW
1	I currently do no physical activity and don't intend to start
2	I currently do no physical activity but intend to start
3	I do some physical activity but not regularly
4	I have been doing regular activity for less than 6 months
5	I have been doing regular activity for more than 6 months

Regular activity is 3-5 times per week for at least 20 minutes each time

SESSION FIVE

Session Five - Objectives

By the end of the session each participant should:

- have selected at least one strategy to deal with any difficulties they have taking medication as prescribed
- have identified a situation in which they find it difficult to follow their diabetes regimen, and set a goal appropriate to this situation
- be able to identify the stages of problem solving
- be able to identify what a relapse is
- understand that how a behaviour relapse or set-back is viewed will be influential in determining whether a behaviour continues to be performed

Session Five - Content

5.1 INTRODUCTION (2 minutes)

Aim: *To describe the main content of the session.*

- Tell the group that the session today has three main aims:
- I) to discuss medications further, including factors that influence taking medication, and how it feels to need medication.
- II) to look at following a self-management regimen in difficult situations.
- III) to give an overview of what has been learnt in the sessions and how this can be applied outside of the programme.

5.2 GOAL SETTING FEEDBACK (8 minutes)

Aim: *For each individual to speak within the group. To hear and reinforce the groups efforts with last weeks goal.*

- Tell the group that firstly you want to hear how people got on with their goals. Suggest you begin. Read your goal aloud and then mention problems or difficulties you had, pretending if necessary, to show that problems are acceptable.
- Ask each participant to provide feedback on their goal from last week using the question below. Emphasise that it is important for them to mention both positive as well as negative experiences.
- Thank each participant for their response and reinforce each person for the effort that they made, regardless of outcome.
- Make a note of any problems people mention, however, do not address problems immediately wait until everyone has reported back and then move on to dealing with these problems.

Question: **Let's go around the group and can each person remind us what goal they set, and tell us how they got on. Say what you managed and whether you had any problems.**

- Structure by behaviour e.g. all exercise problems first.

- Identify what the problem is then within the group examine different strategies to help deal with the problem. Ask individuals to select a strategy that they could try.

- If an individual mentions a problem define what the problem is, then with the group examine different strategies to deal with the problem. Ask individuals to select a strategy they could try.

- Where appropriate challenge negative or false beliefs.

5.3 BARRIERS TO MEDICATION (20 minutes)

Aim: *To uncover the reasons for not taking medicine as prescribed. For the group to identify strategies to overcome this where it is unintentional, and to challenge beliefs where intentional.*

- Raise the issue of non-adherence with the group and brainstorm to explore the reasons for this.

For Example: Some people say that they do not always take their medication exactly as their doctor tells them. They have various reasons for this. I wonder if anyone here feels the same.

- Cycle through problem solving so that i) practical ii) emotional reasons for non-adherence are probed then strategies to deal with these identified.

- Refer to tables to see example problems and strategies. Probes should be used to help elicit both problems and strategies as far as possible.

Question: **Are there any reasons why you sometimes find it difficult, or maybe choose not to take your medication as you have been told?**

Probe: **Practical Problems**

- **Does anyone ever just forget to take their tablets or insulin?**
- **Have you ever stopped taking your tablets or insulin because of side-effects?**
- **Are there any situations e.g. when you are very busy when you do not take your medication?**

Probe: **Emotional Problems**

- **Some people say that they are afraid that taking so many tablets will do them harm, does anyone here feel this way?**
- **How does taking medication make you see yourself?**
- **Some people have said that they do not like to take their medication all the time as it reminds them that they are not completely healthy? Would anyone here not take their tablets for this reason?**

Question: **Are there any strategies you use to overcome these problems?**

Probe: **Strategies to Deal with Practical Problems**

- **Does anyone have any ideas of ways to help you remember to take your tablets?**
- **Did anyone find a way to overcome this side-effect?**
- **Has anyone else had a similar problem? What did you do?**

Problem	**Strategy**
Forget to take pill	- link to other behaviour e.g. eating breakfast - organise pills in box once a week - place reminder notes in prominent places
Side-effects are unpleasant	- discuss changing tablets with doctor
I am too busy to take tablets	- set aside a specific time to take them

Strategies to challenge beliefs

- **Does anyone else think differently about this?**
- **Does not taking medication help you feel as though you are healthy?**

Problem	Strategy
I believe tablets are toxic/addictive	- explain the benefits of the tablets
Taking tablets reminds me I am ill	- help patient to see that they are more healthy with tablets than they would be without - suggest that tablets give them control over their illness

- Ask if anyone would like to set a goal for taking medication. For those who do check that a suitable goal has been set.

5.4 MANAGING DIABETES IN DIFFICULT OR NON-ROUTINE SITUATIONS (30 minutes)

Aim: *To think about how diabetes can be managed in non-routine situations. To learn to plan ahead*

- Say that you have looked at the individual components of the diabetes regimen and now you would like to think about how they all fit together. Suggest that to do this you would like to look at situations in which individuals find it particularly difficult to follow their diabetes regimen.

- Brainstorm examples. Ask each member of the group the situation that they would find the most difficult. Use this to identify situations that the group most commonly has difficulties with.

- If participants can not identify situations that they have difficulty with then general difficult situations can be discussed.

- Help participants to plan ahead for these situations by i) ensuring that the problem has been defined fully and broken down into its component parts,

ii) strategies to overcome components of the problem are identified, iii) a strategy is selected, iv) a goal is set to use that strategy the next time the difficult situation arises.

Question: **What are the situations in which you find it most difficult to manage your diabetes?**

Probe: (make examples quite specific using probes)

- What sort of thing is it that makes you stressed?

- What sort of thing do you think you would be upset about?

Examples: **Busy periods at work lead to poor blood sugars**

Stage of Problem Solving	
Break down components of problem	- When busy there is not enough time to get a proper lunch, meals are missed. - Exercise sessions are missed because I am too tired when I get home from work.
Identify possible strategies	- Take prepared lunch that fits diet, or buy lunch on the way into work. - Plan exercise sessions for weekend. Include family if appropriate.
Identify possible goal	- Plan to take prepared lunch on 3 of the 5 busy days.

Feeling depressed because a blood test at the doctors has shown your blood sugars are too high.

Stage of Problem Solving	
Break down components of problem	- Negative belief that following regimen is pointless as sugars remain high even when following regimen. - Monitoring is avoided.
Identify possible strategies	- Think about reasons why blood sugars may have been high on this occasion. – Increase behaviour in one aspect of the regimen to bring sugars lower. - Remain on regimen until next blood test to see if blood sugar is consistently high or a one off.
Identify possible goal	- Include one more exercise session in regimen. - Stick with regimen for next month and have repeat blood test.

Going on holiday

Stage of Problem Solving	
Break down components of problem	- Meals will be eaten at irregular times which may influence insulin requirements. - No facilities to do exercise as normal. - Unsure of what to do with insulin in a hot country.
Identify possible strategies	- Find out meal times in hotel restaurant and work out changes in insulin before going - Increase walking and swimming activities while on holiday. - Discuss with nurse how to transport insulin.
Identify possible goal	- Make appointment with nurse in the month before the holiday to discuss any necessary changes. - make a goal of swimming in the hotel pool on at least 3 days per week of the holiday

COFFEE BREAK

5.5 SUMMARY OF PROBLEM-SOLVING TECHNIQUES

- Tell group that as they may have noticed when looking at how to deal with difficult situations the same pattern was followed each time.
- Summarise steps of problem solving, giving examples when appropriate.

Summarise:

Step One: **Identify the behaviour to be changed (e.g. diet)**

– Part of the diabetes regimen that could be improved.

Step Two: **Identify what makes it difficult to carry out this behaviour as you would like**

- Break difficulties down into small pieces.

Step Three: Think of strategies to overcome these difficulties

- Take each difficulty in turn and try to find as many strategies or solutions as possible that would help you overcome this difficulty.

Step Four: Identify a goal for the coming week

- Choose one difficulty to tackle over the coming week then choose one strategy to overcome it.
- Make it a goal to try and use this strategy in the coming week.
- Make sure the goal is at an achievable level. It is better to take a small step and be successful than be over ambitious and not make your goal.

Step Five: Choose a reward for completing your goal

- Choose a small treat for yourself if you complete your goal. It is best to avoid foods as treats.

Step Six: At the end of the week check how you got on

- If you managed to complete your goal then give yourself your reward.
- If you did not manage to complete your goal think about what it was that stopped you. Are there things which would help you next time.

Step Seven: Revise/renew goal

- If you did not manage the goal try setting a new goal for the following week, maybe using a different strategy or being less ambitious.
- If you did manage to complete the goal try writing a new goal to take it one step further.

- Say that these steps for changing behaviour can be used for any behaviour.

- Indicate to group that this is the pattern they have used throughout the programme when looking specifically at monitoring, diet, exercise, and taking medication.

- Suggest that these techniques are not just limited to behaviours associated with diabetes, but they can be used in any context and work well when dealing with many different problems.

- Clarify that the main aim is to break the behaviour/problem down into small manageable chunks and deal with each chunk one bit at a time.

5.6 DEALING WITH RELAPSES AND UNFULFILLED GOALS (20 minutes)

Aim *To highlight that because diabetes is an ongoing illness it is likely that at times there will be setbacks in behaviour change and not all goals will be successful. To identify ways in which these relapses can occur. To emphasise that an individuals reaction to a set-back will influence whether the behaviour is attempted again or abandoned.*

- Explain to the group that although the techniques described are likely to help them make behaviour changes there may be times when they cannot manage a goal. Point out that even if they have been successful throughout the group it may be harder when away from the group and the only person to answer to is themselves.

- Help the group to identify what a relapse of a goal is. Make the distinction between goals which are simply not achieved and those which gradually drift off. Use examples if appropriate.

Question: **Can anyone think of a situation where they have not achieved their goal? Can you tell us what happened?**

Summarise:

Example: **Goal is to exercise on four days of the week.**

- Individual does not manage to exercise on any days in the first week because too busy. (Unsuccessful Goal)

- Individual manages to exercise four times a week for two weeks. In the following two weeks they exercise only three times because of bad weather. In the following two weeks only twice a week, etc. After three months the individual will only be exercising once a week. (Initially successful, but relapse over time).

Example: **Goal is to stop eating biscuits with morning and afternoon tea on four of five week days.**

- Only manage to avoid biscuits on two occasions during the week(Unsuccessful Goal).

- Successful at goal for first two weeks. On third week seeing friends in the afternoon means only avoid biscuits in the mornings and two afternoons. After one month drifted into eating biscuits every afternoon. By six months back to the beginning of eating biscuits morning and afternoon. (Initially successful, but relapse over time).

- Tell the group that it is important to be able to recognise when these relapses occur, especially if they are in the form of gradually falling back into old ways.

- A useful way to do this is for individuals to keep their goals explicit, and by checking how they are doing at regular intervals for example every month or so.

- They can then start again if necessary. Suggest that to be able to start afresh it is important to consider the reaction someone may have to relapsing at a goal and how this can affect behaviour.

- Brainstorm how individuals reacted when they had a set-back or did not achieve a goal. Try to draw out both individuals feelings and cognition's about the failure and how this reaction influenced future behaviours.

- Finally, summarise the points below to illustrate that the way someone thinks about set-backs will be an important influence on whether a behaviour is abandoned or attempted again.

Question: **How did you react when you did not meet your goal?**
Probe: **- How did it make you feel?**
- What did you think was the reason that you did not achieve the goal?
- Was it something about the situation or yourself that meant you could not achieve the goal?

Question: **How do you think this reaction influenced your behaviours?**
Probe: **- Were you able to go straight back on your diet or did you stop for a while?**

Summarise:

- People respond differently to set-backs at a goal.
- The same person may respond differently to set-backs with different goals or at different times.
- Some people view the set-back as due to the situation.
- Some people will view the set-back as due to themselves, but as something they can change.
- Some people will view the set-back as something about themselves which they can not change.
- How we think about a downfall is likely to influence how we continue with the behaviour.

- If we think the situation, or something we did but that can be changed, caused the problem then we are likely to try again.

- If however we think the problem was caused by something about us which can not be changed then it is more likely the behaviour will be abandoned.

- Tell the group that all behaviours can be changed but the key is to try and make the changes in small steps.

- Also it can be helpful to think of situations where a goal was completed successfully. This helps us see that we are capable of making the changes. Remind the group that if a goal is not met it is likely that the goal was too ambitious to start with, not that the individual can not change the behaviour.

5.7 PARTICIPANTS QUESTIONS (remaining time)

- Tell group that there is nothing more you plan to cover but you would like to check if anyone has any questions related to anything on the course before you finish.

5.8 SESSION CLOSE

- Tell the group that this was the last session for now but there will be one further session in 3 months time to see how everyone is getting on and the progress they have made with their goals

- Give individuals an opportunity to amend any of the behaviour goals they wish to.

- Thank people for coming to the programme

STAGES OF PROBLEM SOLVING

Step One: **Identify the behaviour to be changed (e.g. diet)**

- Which part of the diabetes regimen could be improved?

Step Two: **Identify what makes it difficult to carry out this behaviour as you would like to**

- Break the difficulties down into small pieces.

Step Three: **Think of strategies to overcome these difficulties**

- Take each difficulty in turn. Try to think of as many strategies or solutions to overcome this difficulty as possible.

Step Four: **Identify a goal for the coming week**

- Choose one difficulty to tackle over the coming week. Then choose one strategy to overcome it.
- Make it a goal to use this strategy in the coming week.
- Make sure the goal is at an achievable level. It is better to take a small step and be successful than be over ambitious and not make your goal.

Step Five: **Choose a reward for completing your goal**

- Choose a small treat for yourself if you complete your goal. It is best to avoid foods as treats.

Step Six: **At the end of the week check how you got on**

- If you managed to complete your goal then give yourself your reward.
- If you did not manage to complete your goal think about what it was that stopped you. Are there things which would help you next time?

Step Seven: **Revise/renew goal**

- If you did not manage the goal try setting a new goal for the following week, maybe using a different strategy or being less ambitious.
- If you did manage to complete the goal try writing a new goal to take it one step further.

BOOSTER SESSION

Booster Session

The design of the booster session is less prescriptive than previous sessions as there is minimal revision of knowledge content, rather the session should be responsive to difficulties that individuals within the group experience. A main focus of the booster session is the problems experienced with maintaining behaviours over time. After introductory discussion about maintenance of behaviour change over time, and revision of problem solving skills, each self-management behaviour should be discussed in turn. Individuals should be asked about what behaviour they are performing now? Is this more or less than when the programme finished? Have there been any slip-ups? Reasons for success and failures can be explored. Using the successes and the paths to success in discussing the failures of others may be a useful technique for provoking discussion and problem solving. This is in addition to the standard problem solving that was examined in the programme. All participants should be verbally reinforced for positive efforts at self-management.

Booster Session - Objectives

By the end of each session each participants should:

- know that there are different levels of maintaining behaviour
- have said how well they have maintained behaviour changes for each area of the diabetes regimen
- have had the opportunity to problem solve any difficulties they experienced with carrying out behaviours
- have had the opportunity to reset any goals they wish to

Booster Session - Content

B.1 INTRODUCTION

Aim: *To welcome people back to the group and explain the purpose of this final session.*

- Tell the group that this final session is to see how they have been getting on with what was learnt in the previous five sessions, and to discuss how their behaviours may have changed over time.
- Remind the group that the purpose of the programme was to help them be better self-managers of their diabetes.
- Ask question.

Question: **Can anyone remind us what we mean by self-management?**

Summarise:

- **Diabetes self-management means you taking increased control and responsibility for your diabetes.**
- Although you may take on the main management role **this does not mean you are alone**; doctors, nurses, family etc still play an important role in supporting, and working with you.
- The **key** to self-management **is self-management behaviours.**

Question: **What are the main self-management behaviours?**

Summarise:

- ❑ Home Blood Sugar Monitoring
- ❑ Diet

- ❑ Exercise
- ❑ Taking medication, tablets or insulin
- ❑ Checking feet
- ❑ Giving up smoking
- ❑ Carrying an identification card or wearing a bracelet

- Say that the programme concentrated on the first four of these. The aim was to give you the knowledge to know what to do but also the skills to use when faced with barriers to these behaviours.

- Say that today you would like to hear how people have got on with these behaviours over the previous 3 months and consider the influence that time has on maintaining these behaviours.

- Ask each individual to briefly say how they have got on in the last 3 months. Tell the group you will go through each behaviour in detail in a moment but first you want to get an idea of how things have been.

Question: **How have each of you got on with your various goals in the last 3 months?**

B2 CHANGES OVER TIME

- Before going through each behaviour in detail say you would like to think about how behaviours and in particular how sticking to a goal may change over time.

- Say a good example of this is a New Year's Resolution. Ask group what normally happens with new years resolutions then work through example of exercising four times a week. Summarise different ways in which individuals may behave over time in relation to the goal.

Question: **What often happens when people set a new years resolution?**

Probe: **- Have you always stuck to your resolution?**
- Has this always been at the level you initially planned?

Summarise

– For the first couple of the weeks in the New Year it is common to stick to your goal, over the following few months this may become more difficult and one of four situations might occur.

- **COMPLETE MAINTENANCE** - this is where an individual has successfully maintained or even exceeded the set level of behaviour (i.e. exercising four or more times a week).

- **SLIP BACK AND MAINTENANCE** - this is where an individual initially maintains their goal, then performs the behaviour slightly less for a period (e.g. exercising twice per week) before returning to the level of their goal (four times per week)

- **SLIP BACK AND SUB-MAINTENANCE** - where an individual does not maintain the behaviour at the level of the initial goal but does maintain it at a lower but still above pre-goal setting level (e.g. continually maintains exercise twice per week).

  Some people will view this as a success while others will think they have failed at their original goal.

- **SLIP BACK AND FAILURE** - where an individual slips back from their original goal and then gives up the behaviour completely.

Question: **What factors do you think influence whether someone keeps their goal up the whole time?**

Probe: **- Can you think of a situation where you set a goal and stuck to it?**
- What factors helped here?

Summarise:

- setting a realistic goal
- integrating it into everyday life
- being determined
- feeling successful, being rewarded and feeling good about achievements

Question: **When someone has a set back what is it that helps them to get back on course or not think they have failed?**

Probe: **- What thoughts help you go back to a goal?**
- What types of goals are you more likely to go back to?

Summarise:

- realising that slip-ups are a natural part of behaviour change
- being determined
- realising if a goal is set at an unrealistic level and resetting goals appropriately
- recognising when successes have been made and being pleased with the achievements that have been managed
- using problem solving skills to tackle difficulties

Question: **What could make someone feel that they have failed at a goal, or make them give up with the behaviour?**

Probe: - Are there any thoughts that make you give up more easily?

Summarise:

- not recognising that slip-ups are to be expected as normal human behaviour
- not recognising that the original goal may have been too ambitious
- not recognising the achievements that have been made
- not using problem solving skills to deal with difficulties

- attributing failure to a personality type which can not be changed (e.g. I'm not the sort of person who exercises anyway)

- Remind group that when having difficulty maintaining behaviour over time it is important to remember that this is normal and that maybe goals need readjusting to suit that period. Use should also be made of the problem solving skills learnt in the main programme to help deal with difficulties.

B.3 REVISION OF PROBLEM SOLVING

- Suggest that it may also be useful to remind yourselves of the general steps in problem solving and then you will see how people have got on with their various self-management behaviours.

- Revise steps involved in problem solving.

Question **Can anyone remind us of the different stages to problem solving that we discussed in the last session?**

Summarise:

Step One: **Identify the behaviour to be changed (e.g. diet)**

- Part of the diabetes regimen which could be improved.

Step Two: **Identify what makes it difficult to carry out this behaviour as you would like**

- Break difficulties down into small pieces

Step Three: **Think of strategies to overcome these difficulties**

- Take each difficulty in turn and try to find as many strategies or solutions as possible that would help you overcome this difficulty.

Step Four: **Identify a goal for the coming week**

- Choose one difficulty to tackle over the coming week then choose one strategy to overcome it.
- Make it a goal to try and use this strategy in the coming week
- Make sure the goal is at an achievable level. It is better to take a small step and be successful than be over ambitious and not make your goal.

Step Five: **Choose a reward for completing your goal**

- Choose a small reward for yourself if you complete your goal. It is best to avoid food as a reward.

Step Six: **At the end of the week check how you got on**

- if you managed to complete your goal then give yourself your reward
- if you did not manage to complete your goal think about what it was that stopped you. Are there things which would help you next time?

Step Seven: **Revise/renew goal**

- If you did not manage the goal try setting a new goal for the following week, maybe using a different strategy or being less ambitious.
- If you did manage to complete the goal try writing a new goal to take it one step further.

- Tell the group that you would now like to go through the four main self-management behaviours that were discussed in the programme. For each one say you would like individuals to say what they are doing now, how this compares to what they were doing at the end of the programme and discuss whether and where they have had successes and setbacks.

- When people give responses probe i) what has helped them succeed, ii) why they have given up, iii) problem solve any specific problems iv) draw out their perceptions of success and failure.

B.4 REVISION OF HOME BLOOD GLUCOSE MONITORING

- Ask question and summarise information to remind group why HBGM is so important

Question: **Can anyone remind us why monitoring (testing) of blood sugars is so important?**

Summarise:

- **HBGM gives an immediate indication of blood sugar levels** at that precise moment.

- This can be **helpful when making decisions about behaviours** that you intend to carry out.
  e.g. if I need to eat something before doing the gardening

- It can also **help you to see the impact of behaviours** you have recently completed.
  e.g. how high was my blood sugar after eating a piece of cake?

- When blood sugars are recorded regularly you **can also look for patterns** and think about how these patterns relate to any change in behaviours.
  e.g. you may notice that giving insulin in the evenings makes your blood sugars a lot lower

- Overall HBGM **allows you to take control of you diabetes** by giving you a window on your blood sugars and how they change with your behaviour.

- Go around the group and ask each individual to report their progress with monitoring. Use probes to explore successes and difficulties with i) maintaining behaviour over time, ii) general problems.

Probe:

- **Were there any strategies you used to help you keep monitoring this often?**
- **What made you return to more frequent monitoring after you stopped for a couple of weeks?**
- **What do you think about the level i.e frequency you set your goal at?**
- **How does anyone else think X has got on?**
- **Were there any days when you missed your monitoring or did not do it as frequently as normal?**
- **What was it that caused you to skip this reading?**
- **Were there any things which made it easier for you to monitor?**
- **Did you start by monitoring more frequently but then gradually stop again?**

B.5 REVISION OF FOOD AND DIABETES

- Before discussing the difficulties of following a healthy eating plan revise the general dietary rules that were described in session two.

Question: **What are the general dietary rules we discussed in the previous session?**

Summarise:

- **Meals should be eaten at a regular time each day.**
- Your diet should be **based on starchy foods.**
- **Aim to eat at least 5 portions of fruit and vegetables per day.**
- Your diet should be **high in fibre.**

- Your diet should be **lower in sugary foods.**
- Your diet should be **lower in fats.**
- **Use unsaturated fats in preference to saturated fats.**
- Large portions of protein foods should be avoided.
- **Salt should be reduced** (this assists in control of blood pressure).
- **Recommended alcohol levels should not be exceeded**

- Tell the group to split into pairs, then explain the exercise described below. After a few minutes ask the group to report what they have discussed to the group. Use probes to increase group discussion if necessary.

Exercise: *Tell the group to split into pairs. Each person should tell their partner which aspect of their diet they have tried to improve in the last 3 months. They should discuss the extent to which they have managed this. What has helped them in sticking to their goal. What situations have occurred that made it particularly difficult to stick to their goal. If they slipped up how did this make them feel, did they return to their diet afterwards?*

Probe:

- **What factors can knock a diet off course ?**
- **What factors have helped you stick to your diet in the previous 3 months?**
- **Were there any occasions when you strayed from your diet?**
- **What was it that helped you get back on track?**
- **How would others feel if they broke their diet? What could the reasons for this have been**

- **Do you eat a high fibre breakfast every day? Does this include weekends?**
- **How many days of the week do you eat ready meals? Why would you use this sort of food rather than cook something fresh? Is there any other way you could save time?**
- **How many pieces of fruit did you eat yesterday? Was this a normal day or do you normally eat more?**
- **What difficulties have you experienced when eating in social situations?**
- **What do you do if friends offer you unhealthy food?**
- **Are there any situations where it has been difficult to follow your diet?**

B6 REVISION OF EXERCISE

- Use the question to remind the group of the benefits of exercise.

Question: **Has anyone experienced any benefits from the exercise they have been doing in the previous 3 months?**

Probe: **- How do you feel in yourself after exercising?**
- **Have you noticed any difference in other health conditions, e.g. arthritis?**
- **Has anyone found that exercising has influenced thier blood sugars?**

Summarise:

- **Exercise can improve blood sugar control.**

- **Exercise can help your heart and lungs work more efficiently.**

- **Exercise can help you lose weight and look better.** Combining exercise and a weight loss diet can be more effective than diet alone.

- **Exercise can help lower your blood pressure.**

- **Exercise can help you feel better mentally and emotionally.** It reduces both stress, anxiety and depression and can help you feel more positive.

- **Exercise can reduce pain and stiffness.** It can help to keep you independent and mobile.

- **Exercise can be good for other health problems e.g. arthritis.** Providing the right exercises are selected, and completed at the correct pace, most conditions can benefit from exercise.

- Ask individuals to report what exercise they are doing now, is this more or less than when they finished the programme.

- If anyone reports low blood sugars after exercise (<4.0) revise what to do to avoid hypoglycaemia.

- Explore any barriers to exercise that have been experienced or are expected to occur and problem solve ways to deal with these.

Question: **Can you each tell us what exercise you have done in the last week? Is this more or less than you were doing at the end of the programme?**

Probe:

- **What can make it difficult to exercise regularly**
- **What is it that has helped you continue to exercise regularly?**
- **What have you done when you experienced a barrier to exercise?**
- **Has anyone used the problem solving techniques discussed in the programme? How did these help?**
- **Do you think you will still be able to exercise during the winter? What will you do if you begin to find it difficult in these circumstances?**

B7 REVISING MEDICATION

- Ask question and problem solve any difficulties people may have had with their medication.

Question: **Has anyone had any difficulties with their medications in the last 3 months?**

Probe: **- Has anyone used any of the strategies mentioned during the programme to help them with taking their medication?**

- How useful have these been?

B8 RELAPSES AND MAINTENANCE OF BEHAVIOURS

- Summarise how time influences behaviour change and the importance of an individuals perspective in determining their success with future performance of the behaviour.

Summarise:

- Time is an important factor in behaviour change.
- Over time the behaviour change may become a part of normal routine so it is easy to carry on the behaviour.
- Alternatively over time situations may occur which make it difficult to continue the behaviour. This may lead to slip-ups or set backs in the behaviour.
- How these slip-ups are viewed by an individual will influence the likelihood of the behaviour being continued.
- People respond differently to slip-ups.
- The same person may respond differently to slip-ups with different goals or at different times.

- Some people view the slip-up as due to the situation.
  (I ate the biscuit because I was out with friends)

- Some people will view the slip-up as due to themselves, but as something they can change.
  (I ate the biscuit because I was hungry and didn't have anything else in the house)

- Some people will view the slip-up as something about themselves which they can not change.
  (I ate the biscuit because I have no will power)

- How we think about a set back is likely to influence how we feel and whether we will continue or make another attempt with the behaviour.

- If we think something we did can be changed, then we are likely to feel more positive or try again.

- If however we think the problem was caused by something about us which can not be changed then we will feel negative about the behaviour and it is more likely the behaviour will be abandoned.

- It is important to realise that very few barriers, whether personal or situational, are not amenable to change when broken down into small stages.

- Whether problem-solving strategies are used or not will influence the likelihood of continued behaviour change.

- Tell the group that throughout the session you have looked at how time can influence behaviour change. Say you would like to finish by thinking of some ways to minimise the negative impact of time.

Question: **Can anyone think of something which would reduce the chances of set-backs happening in the first place?**

Summarise:

- Think ahead to difficult situations and problem solve to come up with a plan and goals to use in this situation.

- Check frequently that your behaviour has not drifted off from your original goal.

- Set realistic targets that can be achieved. People with too high levels of expectations are more likely to be dissatisfied and give-up.

Question: **If a slip-up has occurred what would make you more likely to try again?**

Summarise:

- Remember that behaviour change is difficult so set-backs should be expected
- Attribute set-backs to changeable variables, not personality factors
- Consider whether goal needs resetting
- Problem-solve to deal with the difficulty that caused the set-back.

B9 ONGOING SELF-MANAGEMENT

- Tell the group that before finishing the session they should reset goals for each of the behaviour areas if they wish to. Remind individuals that it might be useful to incorporate something that will help them maintain their behaviours, e.g. planning ahead for difficult situations.

- Suggest that they should use the techniques they have learnt to continue progressing with their diabetes care on their own. Therefore they should feel able to increase their exercise or improve their diet when they feel it is appropriate. This sort of personal decision making is the key to self-management. It is important that when re-setting goals that they are clear about the goal - writing it down makes it clearer and more concrete.